EXHIBIT "WITN3094001/20"

This is the exhibit marked "WITN3094001/1" referred to in the witness statement of Debra Anne Pollard dated 7 May 2019.

(6)

NOTE OF THE RECOMBINANT CLOTTING FACTORS WORKING GROUP HELD AT 12:30PM ON TUESDAY 13 MAY 2003, ROOM 117 EILEEN HOUSE

Present:

Charles Lister	Department of Health - Chair
Karin Pappenheim	Haemophilia Society
Chris Hodgson	Haemophilia Society
Dr Frank Hill	UKHCDO
Christine Harrington	RCN Haemophilia Nurses Association
David Kemsley	London & SE Haemophilia Consortium
Dr Susan Schonfield	Croydon PCT
Mick O'Donnell	Haemophilia Commissioner – West Midlands
Steve Davies	NHS Purchasing & Supply Agency
Dr Claire Bradford	Newcastle PCT
Carl Ashworth	Haemophilia Commissioner – Manchester
GRO-A	Patient Representative
Joanne Wells	Haemophilia Commissioner- West of England
Dr Denise O'Shaughnessy	Department of Health
Zubeda Seedat	Department of Health

WELCOME, INTRODUCTIONS AND APOLOGIES

1. Charles Lister welcomed GRO-A to his first meeting. He introduced Denise O'Shaughnessy, Consultant Haemotolgist, who had joined the Blood Policy Team on secondment. Joanne Wells was attending on behalf of Trudi Mann.

2. Apologies were received from Dr Charles Hay, Mike Maunder, Andrew Whittome, Dr Mark Winter, Sophie Heiser and Trudi Mann.

MINUTES OF THE PREVIOUS MEETING

3. David Kemsley said that the minutes did not reflect the concerns he had previously expressed about the need to have total transparency in the data validation process. David Kemsley had emphasised at both meetings of the working group the importance of the data collection process so that the group could reach a conclusive decision on the mechanism for funding and to help project future revenue consequences. PCTs were under considerable financial pressure already and the group would need to be mindful of the long-term financial impact.

4. GRO-A proposed that the Secretariat should verify the data on the number of haemophilia patients with HIV, with the Macfarlane Trust. He suggested that the number were less than the figures presented at the first meeting of the working group.

Action: Secretariat to verify data with the Macfarlane Trust.

MATTERS ARISING

FINALISED PATIENT PRIORITY ORDER STATEMENT

5. The patient priority statement had been revised to reflect comments made by members. The finalised copy had been circulated to the group.

INFORMATION ON DEPARTMENT OF HEALTH WEB SITE

6. Information on the working group was now available on the DH website. The website included the press release announcing the funding for recombinant clotting factors, remit and membership of the working group, the minutes of the first meeting, and the finalised patient priority order statement. The website would continue to be updated as the work of the group progressed. The website link was available through http://www.doh.gov.uk/blood/rcfwg

DH/COLLABORATIVE COMMISSIONING GROUPS MEETING 25 APRIL

7. Charles Lister said that he attended the joint DH/Collaborative Commissioning Group (DH/CCG) meeting on 25 April. Members of the DH/CCG supported the proposal for a national framework for all products. In addition, commissioners asked to be involved in the validation of the data being collected by UKHCDO on the number of patients receiving recombinant clotting factors. The working group supported the involvement of lead commissioners in the data validation process. This stage would need to be built into the implementation programme.

TENDERING SUB GROUP

8. The first meeting of the Tendering Sub-Group was held on 22 April 2003. The following key points emerged in discussion at the Sub-Group meeting:

- The average price difference between plasma and recombinant products will be used to work out how many units can be afforded.

- The contract would prioritise haemophilia A and B patients in preference to inhibitor patients. It was decided that further information was required about haemophilia patients with inhibitors. Under current arrangements those patients can be prescribed rFVIIa (NovoSeven). Contracting for NovoSeven would be considered when the information is available.

- The need for guidelines to PCTs to ensure that patients in the targeted age-bands are treated with recombinant products.

- PASA would approach the drug companies for quotes for each of the three years for all the recombinant products. A volume banding system would be used.

- If companies are asked for a price reduction for volume, they may require a minimum commitment. However, there were potential problems to this approach.

9. Members of the working group agreed that NovoSeven should be excluded from the initial tender.

10. Steve Davies confirmed agreement to use the accelerated tendering procedures. It was anticipated that the specification for the tender would be issued in June.

Action: PASA to provide an update on progress at the next meeting.

UKHCDO DATA COLLECTION/REVISED PROPOSAL

11. As agreed at the last meeting the UKHCDO had written to Haemophilia Centres requesting data on the number of haemophilia patients over 22. Not all Centres had responded, as a consequence the group was unable to validate the data presented by UKHCDO at the first meeting.

12. Members of the group emphasised the urgency in being able to validate the data previously presented by UKHCDO, so that they could agree a way forward, and prevent any delays in the treatment of recombinant. There was agreement that there would be a number of variables involved in planning, but the group would work on the best assumptions based on the data available.

Action: UKHCDO to complete the data collection process and to present an analysis at the next meeting of the working group.

ALLOCATION OF FUNDS TO PCTS

13. The group awaited data from UKHCDO before discussion on the distribution of funds to PCTs. There was support from a number of haemophilia commissioners at the DH/CCG meeting that funding should be made available to PCTs in line with the patient population for the first three years of the roll-out. There was also support from some members of the group to target the funds to lead PCTs. David Kemsley proposed that funds for London and the South East Collaborative should be allocated to Croydon PCT.

FUNDING OF NATIONAL HAEMOPHILIA DATABASE

14. Charles Lister sought the views of members on a request from UKHCDO to fund the National Haemophilia Database maintained by UKHCDO. Discussion focussed on supporting a project manager post in order to enable UKHCDO to manage and audit data required for the implementation programme.

15. If funding were agreed, the Department would have to make funds available from the recombinant clotting factors budget. There was some reservation from GRO-A GRO-A to use the funds allocated for patient care, for funding the post at UKHCDO. However, there was general agreement that clear and fully up to date data was required to monitor the implementation of the recombinant roll out and that this was an essential part of a project such as this with an £88 million budget. It was agreed that in view of the essential need for data on recombinant use, the project manager

post should be funded, initially for one year, on the understanding that the job description would be written to reflect its role in ensuring the effective roll-out of the programme. Charles Lister asked Frank Hill to prepare a draft job description for consideration by the Department.

Action: Frank Hill to prepare a job description for the project manager post.

NEXT STEPS

16. Members suggested the Secretariat should prepare a timetable, which would help to provide clarity on the implementation programme. There were clearly a number of key target dates, which the group had to work towards to ensure that haemophilia patients start to receive treatment with recombinant clotting factors.

17. Frank Hill suggested a need for a few short papers which would encapsulate the key issues to help develop a framework for implementation. This included:

- Presentation of existing data. Future data being collected and how the data will be used to inform the implementation process.
- Age related roll-out: issues for consideration and planning.
- Patient eligibility document: this would include a copy of the statement by Frank Dobson of February 1998, and the statement announcing current phased provision. The document would also include what is not covered by the roll-out.
- Information on how patients would be informed of the process of implementation and advice through UKHCDO and how patients should be contacted.
- Issues for centres around billing: possibly separate arrangements for children and adults.

Action: Frank Hill to produce a discussion document.

Action: Secretariat to prepare a project plan for implementation for discussion at the next meeting.

DATE OF NEXT MEETING

18. The next meeting would be at 11:00am on Friday 11 July 2003.