EXHIBIT "WITN3094001/23"

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

Roll-Out of Recombinant Clotting Products for all Adult Haemophilia Patients in England: Report of 2003/04

1. The following report provides an outline summary of progress in the implementation of the provision of recombinant clotting products for all adult Haemophilia patients in England in the financial year 2003/04.

2. On 12th February 2003 the Minister for Public Health announced a national policy to make synthetic recombinant clotting products available to all adult Haemophilia patients. This was backed up with the announcement of an additional £88m of dedicated monies to support this policy. The Minister stated that the roll-out would be phased and that the vast majority of patients would be receiving recombinant products by March 2006.

3. The £88m was to be allocated in the following way: -

2003/04	-	£13m
2004/05	-	£21.7m
2005/06	-	£53.4m

4. No details were provided at the time as to how this would be achieved, rather that the Government would work with key stakeholders to design a programme to roll-out access to recombinant products to all patients in England. (Enclosure 1: DH press release 12th February 2003, 2003/0056).

5. In February 1998 provision was made for all children under the age of 16 to transfer to recombinant products and all those older patients subsequently presenting who had not previously received plasma derived products. This cohort of patients had grown up and recombinant treatments were already therefore routinely available to all Haemophiliacs up to the age of 22. (i.e. those born after 26th February 1982).

6. DH set up a Working Group to advise on the phasing in of recombinant clotting factors for Haemophilia patients aged 22 and above. Membership was made up of representatives from commissioners, UKHCDO[1], Haemophilia Alliance, Haemophilia Society and PASA. (Enclosure 2: Membership and Remit of the Working Group.) The Working Group met on 5 occasions in 2003, the first meeting being held on 19th March 2003.

7. During its meetings the Working Group considered the following issues: -

   i) Financial resources available within each year of the roll out programme

[1] United Kingdom Haemophilia Centres' Doctors' Organisation

ii) Potential patient group priority order
iii) Matching patient priority/roll-out to the resources available
iv) Anticipated volumes and prices operating across the 3 year period
v) Methodology for allocating central monies to PCTs

8. The Working Group recognised the lack of historic national data to inform this process and agreed to use the data submitted by Haemophilia Centres to the UKHCDO in making the above assessments as the best available data at the time.

9. In addition to the patients' perspective, as represented by the Haemophilia Society and Haemophilia Alliance, the Working Group received and took into account representations from the Birchgrove Group. (The Birchgrove Group is a self-help group for people affected by the issues of Haemophilia and HIV and HIV/HCV co-infection. The group requested that priority should be given to patients infected with HIV).

10. The DH established a website which posted details of progress of the Working Group and minutes of its meetings (www.dh.gov.uk then click on health and social care topics .... then blood).

11. During the course of its work the Working Group agreed the following: -

i) The roll out of recombinant products would be by patient age group. This would continue the principle established by the previous Health Service Circulars HSC 1998/033 and HSC 1999/999 regarding children under 16 (ref 5 above) and was felt by the group to be the most equitable option available.
ii) A national tender be placed for the additional amount of recombinant products that would need to be purchased with the aim of ensuring that the best possible price was realised for the NHS and that there was consistency of pricing to all Trusts and PCTs across England.
iii) It was agreed that funding of patients receiving recombinant product VIIA would be excluded until year 3 of the programme (i.e. 2005/06.)
iv) Central monies would only be available to meet the difference in cost required in moving adults to recombinant products. Those adults who were *already* on recombinant products would therefore not attract this price support as they were already being funded by their PCTs and had not had their treatment changed in response to the Ministerial announcement.

12. UKHCDO undertook an audit of usage of clotting products by patients in financial year 2002/03 to use as a broad indicative measure of patients' potential usage in future years. This data was subsequently shared with national commissioners for local validation.

13. UKHCDO contacted each Haemophilia Centre for them (a) to confirm the amount of International Units (I.U.) of clotting products used by each patient in 2002/03 and (b) following discussion with the patient about whether they wished to transfer to a recombinant product, to confirm which product the patient would be transferred to. This latter information would inform the tender letting process.

14. The Working Group established a Tendering Sub Group. This group carried out an assessment of the likely volumes of recombinant products which could be purchased out of the nationally available resources in each of the 3 years, taking into account anticipated usage (calculated using the UKHCDO data) and indicative prices (obtained from the drug companies).

15. Thereafter the Working Group agreed that PASA should post an invitation to tender in OJEC in 2003 across the 3 year period in line with the volumes indicated. Responses were requested by 1 July 2003 .

16. In July 2003 the Working Group considered the allegation that the basis of the roll-out on age grounds was discriminatory and contravened NHS guidance. Legal opinion was sought on this which confirmed this approach did not breach article 14 of the European Convention on Human Rights.

17. Commencement of the roll-out was delayed by a further legal challenge which had been raised in judicial review which argued that the DH's 1998 Health Service Circular (HSC 1998/033) on recombinant products for children was in breach of the Disability Discrimination Act. Pending judgement on this point commencement of the roll-out was delayed. The judgement finally granted on 8th December 2003 did not support the challenge and the roll-out then continued as planned.

18. On 7th January 2004 Haemophilia Centres were asked to order 5 months supply of stock for their patients. At the same time PCT Directors of Finance were informed and also told they would shortly be given information on their PCTs' allocations to support the 2003/04 part of the roll-out. It was necessary for Trusts to order 5 months supply of stock in order to fully utilise the central resources available in 2003/04 (i.e. £13m). In effect, Trusts were asked to purchase 3 months stock to be used in 2003/04 and purchase and carry forward 2 months stock into 2004/05. (This approach was to ease the implications of the relative disparity

between the amounts of funding available in each of the 3 years. This constrained the Working Group's flexibility and the pace at which the roll-out programme could be carried out).

19. PCTs were notified of their allocations for 2003/04 in the first week of March 2004 and were asked to expedite transferring this money to the appropriate Trusts.

20. The Working Group recognised the various constraints under which it had to operate in developing a national policy e.g., data gathering, assessment of possible future prices, future national needs, legal challenge etc. This meant that the actual process of ordering stock, placing of patients on recombinant and processing £13m between DoH, PCTs and Trusts had to be compressed into the final weeks of the financial year.

21. In recognition of completion of this first phase of the programme, the Working Group was re constituted and re designated as the Forward Planning and Monitoring Group: Roll-Out of Recombinant Treatment for Adult Haemophilia Patients. Its first meeting was held on 9 February 2004.

September 2004