DHSS PLASMA SUPPLY AND BLOOD PRODUCT WORKING GROUP
MEDICAL SUB-COMMITTEE

The Minutes of the first meeting of the Medical Sub-Committee held at the Central Blood Laboratories Authority in the Crest at 2.30 pm on Thursday 28th April 1988.

PRESENT:

Dr H Gunson (In the Chair)
Dr M Contreras
Dr R S Lane
Dr C Rizza
Dr W Wagstaff
Dr R Moore

Dr Gunson introduced the meeting and thanked everyone for attending. The urgency of the problem regarding plasma supply had initiated the formation of the committee so that data could be accumulated.

1. Apologies for Absence

Apologies were received from Dr Snape but he hoped to join the meeting later.

2. Terms of Reference

Dr Gunson gave details from the letter received from Dr E Harris, the Deputy Chief Medical Officer, of the committee's terms of reference.

The Medical Sub-Committee needed to consider the problem of yields and how much plasma would be required for the fractionation of F8 and F9. The second sub-committee would be looking at financial and distribution issues and would be chaired by Dr M Harris.

The Core Group consisted of everyone from both committees and would hopefully meet June/July with Dr E Harris in the chair. Dr Moore and Dr Pickles would attend both sub-committee meetings.

18 MAY 1988
6/24-

2. "What is Self-Sufficiency?"

Dr Gunson said that this had been discussed at length at another meeting and the CBLA definition was basically when customers do not go to another supplier.

3.1 Dr Gunson read the statement and asked for the views of the committee.

Dr Lane said the statement was still correct.

Dr Wagstaff asked if we had an estimate of albumin usage to take into account. Dr Gunson said no estimate was available. Dr Contreras and Dr Rizza agreed that F8 was the controlling factor and that plasma supply should be based on F8 requirements.

3.2 Yields of Factor VIII

Dr Lane considered 90 miu would be marginal.

Dr Lane enlarged on the history of yields. During 80/81/82 a process yield was talked about - this was what was made as a batch product and the yield was somewhere in the region of 210 iu per kilogram.

This did not take account of QA, interim losses or problems with fractionation which make up the net yield figure which we did not have at that time.

It was considered we could project 225 as a figure but during the summer of 1984 the need to take HIV into consideration became apparent. This meant a change of process which after nine months development produced Factor 8Y. At this stage the process yield was 200 iu at Oxford and the product was much purer. It was transferred to Building 25 at Elstree and the pool size was increased. In 1987 it was transferred to Building 27 and the yields dropped, due to problems with equipment and commissioning, to 140 iu per kilo.

However, the last batch processed was 191 iu/kg. There will be teething problems during the first year which will cause difficulties so the net target yield has been set at 166 iu/kg reflecting a process yield of 185 iu/kg. Obviously BPL will work towards getting the yield back to 200 iu/kg but it may take a year or two to achieve.

To achieve this we need

1) to develop a stable state of manufacture

2) to consider basic improvement in fractionation technology

3) not to have to develop any new viral inactivation procedures.

Introducing a new technology of F8Y has not given an established data yield. A six month uninterrupted run was needed to establish the data.

Whilst it was hoped to improve the 166 iu/kg net yield it must be remembered that commercial companies only get 80-100 iu.

Dr Gunson asked what the haemophilia directors thought of F8Y as a product. Dr Rizza said he had to admit that there had been a core of resistance to NHS material which had carried across to 8Y when it came out, but now he considered things had changed.

Dr Gunson enquired whether a detergent or wet heat treatment would be desirable. Dr Rizza replied that he did not think this was a good idea as 8Y had become accepted as a good material as it was.

Some savings could be made by using 250 units in bottles as there would be less wastage.

Dr Gunson asked Dr Lane if 500 tonnes could be considered as an 89/90 target. Dr Lane replied this would not be enough to give us a reasonable margin if yields did not improve and also would not enable us to get a minimum inventory on the shelves.
Dr Gunson asked what 8Y yields were in Scotland? Dr Lane said he would try to find out from Dr Perry but did not expect them to be comparable as their F8 was differently produced.

It was agreed that Dr Gunson should find out more about production in Scotland.

4. <u>The Plasma Supply</u>

4.1 Dr Lane gave figures showing when we would run out of plasma. If plasma supply remained at its current level of 330 tonnes annually

C/F April 1988	-	500 tonnes
Receive during 88/89	-	330
Input		830
Would process		450
C/F April 1989		380
Receive during 89/90		330
Input		710
Process		550
C/F April 1990		160
Receive during 90/91		330
Input		490

Plasma supply would be exhausted by Christmas 1990 and by August BPL would run out of marginal reserve.

Dr Lane said he needed to know what Dr Rizza and his colleagues requirements were then we could get to grips with the situation and approach the matter logically.

4.2 Appendix II indicated that the target figures would need to go up by 25% to reach the new amount required.

4.3 Consideration of options for supply of FFP.

i) It was reported that donations were dropping.

ii) Dr Rizza presented a map plus Supraregion Data.

Dr Gunson thought from this data it should be possible to calculate how much F8Y each patient needed and therefore could work out how much plasma on a yield of 166 iu/kg would be needed to supply the necessary F8Y. This could then be the basis for the 88/89 targets. Some regions, particularly the Northern, had problems reaching existing targets.

iii) Other Options

Dr Gunson suggested that rather like the Swiss system the CBLA could set up plasma pheresis centres in places like Milton Keynes. Dr Contreras considered the RTC's were in a better position than CBLA to run plasma pheresis centres with possible funding from the CBLA.

5. Any Other Business

There was no other business.

6. Date of Next Meeting

Monday 6th June at CBLA, Elstree in the Crest.