COAGULATION FACTOR WORKING PARTY

To:	*Prof CA Ludlam*	*Prof GDO Lowe*	***From:***	*Miss J Pelly*
	Dr J Anderson	*Dr W Murray*		
	Dr P Cachia	*Dr RJ Perry*		
	Dr P Clark	*Dr CV Prowse*		
	Dr E Chalmers	*Dr C Tait*		
	Prof IM Franklin	*Dr A Thomas*		
	Dr L Horn	*Dr ID Walker*		
	Dr A Keel	*Dr HG Watson*		

Copy to: *Mr A Macmillan Douglas*

NOTICE OF MEETING

The next meeting of the Coagulation Factor Working Party will be on:-

Monday 25th March 2002 at 2pm

In the

Haemophilia Centre Seminar Room, Royal Infirmary, Edinburgh.

I will circulate an Agenda nearer the date, please let me know if you have any items you wish to be included.

COAGULATION FACTOR WORKING PARTY

Minutes of Meeting of Thursday 7th February 2002, 2.00pm to 5.15pm, Haemophilia Seminar Room, Royal Infirmary, Edinburgh.

Present:	Prof CA Ludlam	Prof IM Franklin
	Dr J Anderson	Mr A Macmillan Douglas
	Dr E Chalmers	Dr P Clark
	Prof GDO Lowe	Dr RJ Perry
	Dr AE Thomas	Dr CV Prowse
		Miss J Pelly
Apologies:	Dr P Cachia	Dr C Tait
	Dr L Horn	Dr ID Walker
	Dr A Keel	Dr HG Watson
	Dr W Murray	

ACTION

1. Apologies

See above.

2. Minutes of the Meeting on 11th May 2001 at the Haemophilia Centre, Royal Infirmary, Edinburgh.

The Minutes were agreed as a correct record.

3. Matters Arising.

All matters arising were covered on the agenda.

4. Risks of Transfusion

4.1. As a result of the recommendations following the investigation by the Health and Community Care Committee into Hepatitis C transmission, the Clinical Standards Board (CSB) has been auditing the standard of information given to patients. David Steel, the Chief Executive of CSB, met with IMF to find out how SNBTS complied with the current generic standard.

AMD informed the group that as a result of the Burton judgement SNBTS has changed its public position in relation to the risks associated with transfusion and now emphasises that it is not zero risk. This position is in line with all UK transfusion services. The Clinical Users' Group is currently discussing provision of much fuller information for patients receiving a transfusion. GDOL suggested consideration could be give to including examples of comparative risks in the patient information.

ACTION

The provision of improved information to patients still receiving plasma derived coagulation factors was discussed. SNBTS can only supply patient information that complies with the requirements of the regulatory authority and has been approved by them. However, further information can be supplied to clinicians on specific request to facilitate their conversations with patients. It was agreed that CAL would write to Elspeth McIntosh requesting any additional information he required. The HDs could then use this to prepare a draft patient information leaflet for consultation with CSB. It was agreed that a draft would be tabled for discussion at the Annual Meeting.

CAL

HDs
JP

4.2. The CJD Incidents Panel document was discussed and it was agreed that it should be considered a consultative document at this stage. It was generally felt that it was ill thought out in terms of helping people who may have been exposed to all types of CJD and did not give clear guidance for reporting incidents. IMF had tried to report the incidents associated with SNBTS donors using their system and it had not proved satisfactory. This information had therefore been given to AK for communication directly to the Department of Health.

RJP reported that the categorisation of risk was based on the original assessment which did not take into consideration any clearance of prions in the manufacturing procedure which is the one area where there is scientific data. An updated assessment has been compiled by DNV which is to be subject to peer review including MSBT and SEAC. A small expert group is to consider how the risk associated with plasma products should be amended to account for the results from clearance studies and the risk category may change in the light of this. The risk category is critical in determining the action to be taken and it is possible that many plasma products may fall into the low risk category.

Now the CJD Incidents Panel document has been released for consultation, IMF has notified them and the HDs of the 2 donations affecting batches of factor VIII, DEFIX, IVG and albumin manufactured during 1986 and 1987. The batch numbers had not been included in his letter but IMF agreed to write formally to each HD providing this information. The HDs agreed that they would circulate a letter with some urgency to patients notifying them of the situation. HDs to send comments on the draft letter to GDOL by 15th February 2002.

IMF/RJP

HDs

The HDs agreed that this letter should be sent to all patients treated with factor VIII and IX concentrates between 1st January 1987 and 31st December 1989. HDs to construct lists of patients treated in this window from their own records and from the UKHCDO database. GDOL would draft an additional letter to be sent to all other patients. These letters to be ready around 18th February 2002 with the aim of sending them out at the end of the month. Each HD would write to Dr Frank Hill to seek information from the UK database. CAL would write and notify Dr Hill to expect these letters.

HDs

GDOL
HDs

HDs
CAL

ACTION

The HDs and SNBTS would prepare press responses for release in answer to any media coverage and for providing information for Trusts. The Haemophilia Society would be notified just before the letters are sent out. An SOP for dealing with any future events to be drafted and discussed together with any feedback received from this situation at the Annual Meeting. — HDs/AMD; CAL; ALL

5. Liberate®/Liberate®HT

5.1. CAL reported that it had been confirmed on Monday of this week that funding and recombinant factor stocks were now available to allow all patients to be offered treatment with recombinant product in this financial year and for 2002/2003. However, the HDs felt there would still be a residual need for approximately 2mIU of plasma derived FVIII and 0.5mIU DEFIX. AMD suggested that a representative from NSD again be invited to future CFWP meetings. This was agreed, CAL to write to Deirdre Evans. — CAL

5.2. JP reported that the studies on Liberate®HT were ongoing in Poland but all the Scottish patients were now back on recombinant product but that follow-up of patients on the study would continue.

6. HIPFIX

RJP confirmed that the product is now licensed and will be available for supply at the end of March. He will notify the HDs formally of the launch date and ask for an estimate of demand. — RJP

7. rFVIIa

It was noted that trials of rFVIIa are currently ongoing in coumarin reversal. GDOL said he was not aware of any results as yet. AT felt that because of the very short half-life of rVIIa it may only be effective in moderate overdose and that there would still be a requirement for a prothrombin complex concentrate.

8. Prothrombin Complex Concentrate (PCC)

8.1. S/D DEFIX
JP informed the meeting that the clinical trial of S/D DEFIX in coumarin reversal was about to start. The HDs requested a copy of the protocol. — JP

8.2. Four Factor Concentrate
CAL informed the group that he is now uncomfortable giving a 3 factor concentrate to patients with life threatening bleeding. The HDs were of the opinion that there is a good theoretical rationale for a 4 factor concentrate and this is what the BSH and SIGN guidelines recommend. There are 2 unlicensed products available. CAL asked when SNBTS consider they might have a 4-factor concentrate available. CVP and RJP informed him that it would depend on whether SNBTS produced a PCC which is no more thrombogenic than DEFIX or a non-thrombogenic one which will take longer to develop.

ACTION

The very earliest any 4 factor PCC would be available would be a clinical trial commencing sometime in 2003. It was agreed that SNBTS should progress planning a 4-factor concentrate and bring proposals forward at the next meeting. CVP noted that the evidence base for use of 4-factor concentrate for coumarin reversal was a comparison of plasma with 4-factor PCC or 3-factor plus factor VII. Three factor PCC was not assessed, although it is known to correct the INR in such cases (data available for DEFIX and HTDEFIX). **RJP/CVP**

9. Fibrinogen

JP reported that the study in congenitally deficient patients is ongoing although only one patient has been treated to date.

A protocol has been developed by P Clark in collaboration with the investigator, Prof Peter Hayes, for a pilot study in 20 adult patients with acquired fibrinogen deficiency undergoing minor elective procedures. This protocol will now be submitted to the Trial Monitoring Committee for review. JP agreed to send copies of the protocol to CAL, LH and AT. **JP**

CAL raised his concern over the discrepancy between the fibrinogen assay result obtained by his laboratory and CVP's on one particular sample. CVP agreed to see if any sample was left for CAL to do a repeat test on the same sample that had been tested at CVP's laboratory. **CVP**

10. Fibrin Sealant/Thrombin

JP reported that the study of Fibrin Sealant in liver surgery in Birmingham is scheduled to start at the end of February.

The design of a study of thrombin in the treatment of pseudoaneurysms is under discussion with the Medicines Control Agency.

11. Methylene Blue Treated Plasma

The Haematology Audit Group in Scotland (HAGIS) are currently setting up an audit of treatment of TTP patients. CVP reported that there had been a publication from a group in Spain reporting on the use of MBT:FFP in TTP.

AMD informed the group that he believed that a decision to import non-UK FFP for use in patients born since 1st January 1996 would be made before the end of March. SNBTS are looking at methylene blue treatment followed by filtration to remove the methylene blue for both fresh and frozen plasma. The HDs asked to be kept informed of the situation. **AMD/IMF**

12. Adverse Events

No adverse events had been reported.

13. Product Usage

JP circulated graphs of product usage to the end of December 2001.

ACTION

14. AOCB

CVP reminded the HDs that SNBTS are looking for ITP patients to be recruited on to the liquid immunoglobulin study. **HDs**

A committee is being established to update the UKHCDO guidelines for treatment of patients for final approval at the UKHCDO AGM in October. They would be grateful for any views. **ALL**

The CFWP were informed by CAL of the Haemophilia Alliance which is a national partnership of all groups involved in the delivery of care and the patients. They have produced a service specification that defines haemophilia care standards.

15. Date of Annual Meeting

CAL agreed to ask Dr Armstrong to attend and chair the meeting. The date may have to be changed to accommodate his schedule. **CAL**

16. Date of Next CFWP Meeting

The next meeting will be held on Monday 25th March 2002 at 2pm in the Haemophilia Seminar Room, Royal Infirmary, Edinburgh.