Minutes of the First (Extraordinary) Meeting of the UK Haemophilia Centre Directors' Organisation Executive Committee held at the Lansdowne Club, London on Tuesday 30th January 1996.

PRESENT: Chairman: Dr. B.T. Colvin

Dr. G. Dolan
Dr. P.L.F. Giangrande
Dr. B.E.S. Gibson
Dr. K.K. Hampton
Dr. C.R.M. Hay
Dr. F.G.H. Hill
Dr. P.M. Jones
Dr. C.A. Lee
Dr. R. Lee (representing Dr. S.V. Davies)
Dr. C.A. Ludlam
Dr. E.E. Mayne
Prof. F.E. Preston
Dr. G. Savidge
Miss R.J.D. Spooner
Dr. J.T. Wilde

Apologies for Absence

Dr. A. Aronstam
Dr. P. Bolton-Maggs
Dr. S.V. Davies (represented by Dr. R. Lee)
Dr. I.M. Hann
Prof. G.D.O. Lowe
Dr. V.E. Mitchell
Dr. B.A. McVerry
Dr. R.F. Stevens
Dr. C.H. Toh

1. Chairman's statement

The Chairman welcomed Dr. Dolan and Dr. Wilde who were attending an Executive Meeting for the first time and he thanked Dr. Richard Lee for coming from Exeter to represent the South West. He then read a written statement (Appendix A). Dr. Colvin then invited Dr. Lee to comment.

Dr. Lee tabled a written summary of the background to the sending of the letter to Mr. Dorrell. She said that she had tabled a questionnaire for completion to Regional

Representatives and UKHCDO members at the AGM. No alterations were suggested to the format of the questionnaire either by the Regional Representatives or by those attending the AGM and indeed many people filled the questionnaires in at the AGM and handed them back to her that day. Most Comprehensive Care Centres had replied and a total of 44 replies had been received. Dr. Lee included with the summary a copy of a newspaper cutting of Mr. Dorrell's speech in October which had prompted her to write the letter which Dr. Colvin had also signed. Dr. Colvin said that he had had two letters from Directors regarding the letter sent to Mr. Dorrell and invited Dr. Savidge to speak.

Dr. Savidge said that a number of Centres were using recombinant factor VIII and that a Recombinant Factor VIII Users Group had been formed, the first meeting having been held in September. He noted that VAT at 17.5% was to be introduced on the purchase of recombinant factor VIII at very short notice and the Users Group had decided to attempt to persuade the government to reverse this decision. He said that Dr. Colvin could not be involved in this effort since he was Chairman of UKHCDO. In October the Group had decided that the best time to make a move would be after bills including VAT had begun to be received by the Centres in December. He said that Dr. Colvin had been kept informed that the Recombinant Users Group was planning this move. UKHCDO was a charitable trust and therefore could not make a political move without losing its charitable status. He thought that the letter sent by Drs. Colvin and Lee was not representative of the views of UKHCDO and was not very sensible. He was astonished that the Executive Committee had not been consulted before the letter was sent out and he put four points to Dr. Colvin about this.

1. Information given in the letter was not correct.

2. Dr. Colvin should not have signed the letter as Chairman of UKHCDO.

3. The statistics in the letter were non-sensical.

4. He predicted that the letter would convince the Department of Health that UKHCDO was divided regarding the care of the patients.

Dr. Savidge had discussed this issue with Dr. Hay, Dr. Giangrande and Professor Preston before writing to Dr. Colvin to criticise his action. He believed that the AGM held in Manchester in September was under subscribed and therefore was not representative of UKHCDO and he further stated that he was very unhappy about being in an Organisation that acted in this high handed way.

Dr. Colvin invited Dr. Mayne to comment. She said that it was understood that all members of the Executive Committee tried to do the best for their patients but that each had a different approach. She too had written to Dr. Colvin and Dr. Lee about what she regarded as an error of judgement. She wished that the letter to the Department of Health had not gone out so quickly and felt that Dr. Colvin should not have countersigned it as Chairman of UKHCDO. She suggested that the best way forward was to

1. Form a new Task Force to re-write the document on therapeutic recommendations.
2. Note that the Recombinant Users Group would continue independently of UKHCDO and not as a Working Party of the Organisation, though there would no doubt be some contact between the two groups.
3. Revise the relationship with the DOH's representative(s) so that they would only come to those parts of Executive Committee meetings to which they were specifically invited.

Dr. Ludlam welcomed Dr. Mayne's comments. He thought that it would be helpful for the Executive Committee to know more about the Recombinant Users Group which Dr. Savidge then said had been set up for those Directors who were using Kogenate. He said that this was not an advertising move and that the first meeting had been attended by Bayer representatives and a number of Haemophilia Centre Directors. He felt that something needed to be done outside UKHCDO although the Group would perhaps have a minor reporting role to UKHCDO. Since the imposition of VAT the Group had been expanded to include all companies who had a VAT problem i.e. Baxter, Armour and Novo Nordisk and the next meeting would be on Friday 2nd February. He believed that all known users of recombinant factor VIII were invited. Dr. Ludlam asked if the Group would continue if VAT ceased to be charged on these products. Dr. Savidge said that as the UKHCDO had made no recommendations regarding recombinant factor VIII the User Group would look into this. Members would be able to work out the best business methods for getting the material, and would try to get VAT problems resolved.

Dr. Hay said that he thought that the letter to Mr. Dorrell had been sent too quickly but would not cause long term harm. He saw no reason why the Recombinant Users Group should be limited to people already using the materials and he hoped that the Recombinant Users Group Meetings Minutes would be available to UKHCDO members. He agreed that the therapeutic recommendations document should urgently be revised and he would very much like to be involved in this process. Professor Preston said that he thought the letter to Mr. Dorrell was an error of judgement but he also thought that the Recombinant Users Group was an error of judgement. He was worried about some individuals being particularly involved with some companies. Dr.

Savidge said that the Recombinant Users Group had nothing to do with UKHCDO. It was originally organised by Bayer but now a number of other companies were involved. Advisors to BPL were on the UKHCDO Executive Committee and it would not be consistent to allow this and to object to the Recombinant Users Group. Dr. Christine Lee said that recombinant factor VIII was a drug and therefore would be subject to VAT and this could not be avoided. Dr. Jones said that he would like to see a scientific review of the properties of recombinant coagulation factor concentrates. He agreed with Professor Preston about the involvement of the drug companies and this was the reason for the declaration of interests being required by UKHCDO of their Executive Committee Members. He was not convinced that recombinant factors were safer than biological factors and this had not yet been proved. Dr. Hill agreed with Dr. Jones and thought UKHCDO needed clear recommendations on how to treat patients as soon as possible. In his view there was a lack of scientific information on recombinant concentrates and information was especially needed if the materials were to be used for very young children. Recombinant factors had an important role but UKHCDO also needed to consider potential side effects. UKHCDO should concentrate on recommending treatments and not be concerned about VAT. Dr. Ludlam was concerned about potential conflicts of interest with commercial companies and he suggested that a declaration of interests by Directors should be made annually. Dr. Savidge asked what the situation was for Directors employed by NHS Trusts that had an interest in a particular drug company or companies. Dr. Mayne said that was not so much UKHCDO's concern but it was individual Directors financial support from drug companies which was relevant. After brief discussion it was agreed that the Executive Committee should consider the situation regarding the declaration of

interests at their next meeting.

Dr. Savidge thought that irreparable damage had been caused to recombinant users by the letter to the DOH and that a damage limitation exercise needed to be considered by UKHCDO. He wondered whether the situation which had arisen regarding the sending of a letter to Mr. Dorrell would ever happen again. Dr. Hay said that the DOH had devolved the responsibility for allocating resources to the Health Authorities and the letter from Dr. Colvin and Dr. Lee would make no difference to the purchasers. Dr. Giangrande thought that the letter to Mr. Dorrell was unfortunate but was sent with the best of intentions and no damage had been done. He thought it was important to have a Recombinant Users Group with short term interests which should not be under the influence of drug companies and interested Directors should not be excluded from the Group. Dr. Hill said that the UKHCDO Executive Committee should draw up scientific evidence and plans for the future use of the recombinant products. Dr. Gibson felt that she represented the small users and that new guidelines on the treatment of patients would be very helpful.

Dr. Colvin said that he understood that an error of judgement had been made and he regretted that this had occurred. The letter to Mr. Dorrell had been written in good faith and he strongly believed that it had not compromised UKHCDO's position. The issue of Chairman's action was complex but it was essential that the Chairman should be able to take appropriate action when necessary. He had spent a great deal of time consulting with the officers (Dr. Hay and Dr. Ludlam) and with Dr. Mayne over the past two years and would continue to do so. He could not promise that no Chairman's action would be taken in the future. Dr. Colvin said that there had been no consensus of opinion on the best type of concentrate to offer patients until now but it was clear

that the time had come to undertake the task of reaching an agreement. Dr. Jones suggested that a Working Party on Recombinant Factor VIII should be set up. Dr. Savidge pointed out that the Charity Commissioners' regulations specified that organisations with charitable status should not have political involvement. Dr. Colvin believed that the Recombinant Users Group could assist UKHCDO but was concerned that it might not be easy for the two organisations to co-operate. He would like to add to the Agenda for the next meeting an item on the relationship of the UKHCDO with the DOH. **This was agreed.**

2. Revision of the Recommendations on the Choice of Therapeutic Products.

The Chairman asked Dr. Mayne to comment on this. She said that there was still a lack of uniformity of opinion regarding the use of recombinant products. She felt that a new document should be drawn up by not more than 5 directors in a specified time frame. She thought that there should be good representation of young Directors on the Task Force and that it should be possible for the revised recommendations to be ready by the Spring of 1996. Dr. Savidge said that the Department of Health complained about the last recommendations document which had been published and Dr. Hay thought that UKHCDO should be wary of recommending unlicensed products. Dr. Jones said that he was less than happy with the statement that the recombinant products were safe. Dr. Ludlam thought that UKHCDO should not rush into a Working Party on Recombinant Products but should concentrate on re-writing the recommendations and Dr. Colvin suggested that the following people should join the Task Force:- Drs. Hay, Savidge, Christine Lee, Dolan and Gibson. Dr. Savidge thought that it would be wrong for the Executive Committee to decide immediately about the formation of a Task Force and suggested that this should be discussed again

on the 12th February. **This was agreed.** Dr. Savidge said that small centres should be represented and Dr. Hay pointed out that Dr. Gibson would be representing the small centres. Dr. Hill said that any recommendations regarding the use of recombinant products should be backed fully by scientific information. Dr. Colvin thought that to delay the publication of the recommendations until rock hard scientific evidence was available would not be sensible.

Dr. Colvin summarised as follows

1. The document on the Recommendations on the Choice of Therapeutic Materials would be revised
2. A Task Force of 5 people would be set up to write the revised recommendations and that membership of the Task Force would be agreed on the 12th February
3. A Recombinant Working Party had been proposed and should be discussed at the meeting on the 12th February.

This was agreed.

3. <u>The Imposition of VAT on Recombinant Products</u>

Dr. Jones said that the imposition of VAT was a matter for the Haemophilia Society to take up and was not for UKHCDO to consider. Dr. Giangrande thought that the drug companies had the responsibility of challenging the imposition of VAT on recombinant products. **It was agreed** that this matter should not be pursued further within UKHCDO.

4. <u>Relationship with the Department of Health</u>

Dr. Colvin said that the annual meeting of the Officers of UKHCDO and representatives of the DOH was to have been held today (30th January) but had been

postponed because of the Executive Committee meeting.

Dr. Mayne said that the DOH representative should not expect to come to all the meetings but Dr. Hill thought that UKHCDO should control but not cut links with the DOH.

After discussion, it was agreed that Dr. Rejman should be invited to lunch and the afternoon sessions of the UKHCDO Executive Committee meetings but should not receive a copy of the Minutes of the meetings.

Dr. Colvin said that previous meetings with the DOH had been helpful and recommended that these continue. This was agreed and it was also agreed that the Executive Committee should decide on the items to be discussed.

The meeting closed at 1.45 p.m.

28.03.96

CHAIRMAN'S STATEMENT
30 JANUARY 1996

At the Annual General Meeting of UKHCDO on 29 September 1995 "concern was expressed at the lack of adequate funding for factor replacement therapy, and it was acknowledged that UKHCDO should continue to press the Department of Health for increased resources. Dr Lee presented a form regarding the use of recombinant Factor VIII and asked that Directors should return the completed form to her as soon as possible".

In late October Dr Lee analyzed the results and suggested that a letter should be sent to the Secretary of State since he had recently spoken on the subject of committing "real resources and management support" to ensure that the most up-to-date knowledge of effective treatments is made available to clinicians. I was sent a draft of the letter which aimed to address the difficulty of obtaining recombinant Factor VIII because of inadequate resources. I took Chairman's action to countersign the letter because I believed the content to be in accord with UKHCDO policy and the discussion which took place at the AGM.

In early December a copy of the letter was circulated to Directors together with a full summary of the survey (which had not been sent to the Department of Health) and we have received a standard reply from Dr Andrej Rejman (Senior Medical Officer). His reply is predictable and as usual emphasises the purchaser/provider split in the allocation of health care resources. As you know Dr Rejman would have seen the results of our survey in the usual way and I do not believe that our position has in any way been prejudiced by this correspondence.

I know that some colleagues feel that it would have been better to wait for a meeting of the Executive Committee before writing to the Department of Health and that the letter could have been clearer and more definite in its content. I understand their position and I remain as ever committed to implementing the policy of UKHCDO in all matters, now and in the future.

I believe that this issue highlights the need for UKHCDO to address, with some urgency, the clarification of the indications for recombinant Factor VIII and the revision of the recommendations on the choice of therapeutic products. In addition we must discuss the implications of the VAT regulations with respect to recombinant products since the imposition of VAT on recombinant Factor VIII and other similar products is a severe cost pressure for purchasers. It is for this reason that I have called today's Extraordinary Meeting.

GRO-C: B T Colvin