IMMEDIATE

Our Ref: Fahy310

Mr Fahy PS/PS(H)

From: Dr A Rejman CA-OPU2

Date: 3 October 1996

Copy: Dr Shepherd PR/Off
Dr Metters
Dr Winyard
Mr Staniforth
Dr Mann
Mr Spellman
Mr Guinness
Mr Dobson
Mr Newton
Dr Moore CA-IU
Ms Heaney
Mr Burnett
Mr Pugh
Ms Corrigan
Ms Towner
Dr Keel SHDD
Dr Ludlow WO
Dr Mock DHSS NI

UKHCDO GUIDELINES

1. I have this morning attended the first part of the UKHCDO AGM at the Royal Free.

2. It has been decided not to publish the guidelines at the present time, because some of the senior officers of the organisation have been informed by the MDU that they may lay themselves open to legal challenge under liability and the MDU will not cover them for this. My understanding of what will happen is that the guidelines can be made available by haemophilia treaters during their discussions with their home provider trusts as well as with purchasers. These will be told that the guidelines will be published in due course once the indemnity aspects have been sorted out. There is to be a meeting in NW Regional Office tomorrow with purchasers about the guidelines.

3. I am sending you a copy of this latest version of the guidelines by hand and I will be sending copies by grid to copy recipients. If they urgently need to see the full latest version, could they please contact my secretary who will fax them to them, but they do stretch to 31 pages.

4. The crucial point in respect of the recommendations regarding recombinant Factor VIII are on pages 15-16, and as previously predicted they set out a list of priorities with previously untreated patients being top followed by Hep C negative, Hep C positive and finally HIV positive patients.

5. On page 19, there is a reference to review of the guidelines. I am faxing this to colleagues in CA-IU and in territorial departments so that they may determine whether they need to take any action about the way this section has been phrased. What it states is that an advance draft copy of these guidelines was reviewed and

approved by the following, including the Departments of Health at the Scottish Office and Welsh Office. Dr Ludlam stated that the Northern Irish office had also verbally approved them. I suggested he check carefully with Dr Mock bearing in mind a conversation I had with her yesterday.

6. They also included in this list a statement that the Department of Health for England suggested minor modifications which were incorporated in the final document. I pointed out, as the UKHCDO senior officers and members were aware, DH had not approved the guidelines. I therefore suggested that a gap of at least one line should be placed between the reference to SHHD and WO and DH for England. This was not acceptable to the senior author of the guidelines, who just suggested putting a full stop after WO.

7. Although the treaters that were present at the meeting, and needless to say there was not 100% attendance, are aware of DH line, it may well be that purchasers will interpret this section as implying that DH has approved these guidelines. I would ask Roger Moore and other appropriate copy recipients to consider how best to make sure that purchasers and provider trusts are made aware immediately that DH has not approved these guidelines.

8. I would also ask for advice from copy recipients as to whether the Department should write formally to the Chairman of the UKHCDO stating that we do not accept the reference to the Department of Health and we either want it totally removed or at the very least it made plain that DH does not approve the guidelines. SHHD and WO will wish to consider whether the wording used is acceptable to them.

9. On pages 26-29, there is reference to the price of Factor concentrates. I suggested that this might be appropriate to give purchasers some idea of the differences in price. Against my advice in August, the list price has been used in the tables. There is a brief reference to "discounts may be negotiable". However, what this implies is that for instance BPL's high purity Factor VIII costs 48p a unit, in comparison with each of the recombinant Factor VIII at 52p a unit. This is unlikely to be helpful to purchasers, since they may feel that there is little price difference, whereas those that actually deal with this know that one can obtain the plasma derived Factor VIII product at 25p a unit with no difficulty, whereas there is very little discount in most cases for recombinant Factor VIII, and hence the latter is twice the price.

10. The listing of price, may also do harm to BPL, since their high purity product is quoted at 48p a unit whereas Alpha's new dually inactivated product, licensed on 2/10/96 is only 39p a unit. Perhaps Mr Guinness could discuss with BPL why they still maintain a fictional list price.

11. I did also point out the risk that treaters ran of purchasers looking at these prices and saying well if the recombinant is only 4p a unit more expensive, then they will pay that extra 4p but expect their patients to be treated with recombinant.

12. Happy to discuss, although I am just about to disappear back to the Royal Free for a session on hepatitis C litigation. My secretary will be able to get hold of me.

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EH