Williamson Sue

From: Williamson Lorna
To: Wesley David; Snape Terry; Savery Barry; Williamson Sue
Subject: Minutes of our contract meetingwith Octapharma.
Date: 06 August 1997 12:13

Sorry for the delay in getting these out- David very kindly approved them as he was there for the whole of the meeting.

<<File Attachment: MIN107.DOC>>

It would be helpful if the following could be borne in mind:-

Barry - if you can negotiate a 1 -year renewable contract this will give us maximum flexibility with methylene blue coming online in the next 12-18 months. I'll brief Patrick Sullivan tomorrow to highlight the financial implications of all the start plasma coming from our zone.

Angela//Terry - I heard from Ian Franklin that SNBTS were thinking about methylene blue from this autumn. I'll try and find out where that leaves SNBTS in respect of Octapharma.

David - thanks for you later note and hope you had a good holiday. We are agreed that we should still exclude first time donors as you mentioned, since later sero-conversion may mean loss of the pool. It would be very helpful if you could act as the link to MCA. We're having a zonal group meeting tomorrow to discuss plasma supply - I'll suggest to Jim Knipe that he contact you directly to sort out logistics.

We are not going to get specific IT changes in PULSE (?never), so Mike Brittain is writing a workaround.

Thanks Lorna

NOTES FROM MEETING BETWEEN NBA AND OCTAPHARMA TO DISCUSS IMPLEMENTATION OF OCTAPLAS IN THE UK.

HELD AT NBA HQ, WATFORD, ENGLAND 10TH JULY 1997

Present: Octapharma - Kim Bjornstrup (Vice President)
- Tor-Einar Svae (General Manager)
- Barbara Glantshnig (Quality Assurance)
- Keith Lawson (UK Manager)

NBA - Dr Angela Robinson (Medical Director)
- Terry Snape (Technical Director, BPL)
- David Wesley (BPL)
- Barry Savery (Finance Director)
- Dr Lorna Williamson (Chair, Virally Inactivated Plasma implementation group).

1. General issues.

The purpose of the meeting was to open discussions on how the UK Transfusion Services, through Octapharma and the NBA, could provide user hospitals with a choice of standard FFP or Octaplas at around the time the Ocaplas licence is granted. It was agreed that in the UK Octaplas should be considered a joint product of the Transfusion Services and Octapharma, and could be marketed by both parties. This would not involve BPL. Product liability would rest with Octapharma in the first instance.

2. Contract.

This could largely be based on the Clinical Trials contract, and should allow maximum flexibility on total volumes processed.
Action: Octapharma to provide first draft to Barry Savery.

3. Information leaflet.

Octapharma expressed some concerns regarding both the content of the leaflet and that the fact that it would be available many months before Octapharma were legally able to do any marketing. AR explained that UK Transfusion Services had been asked to provide this leaflet by the Department of Health, and that this was not negotiable. The MCA had also approved the content. LW pointed out this was an ideal time for users to begin to consider purchase of Octaplas, as prolonged delays would miss the business planning cycle for 1998-9.

The leaflet was still in draft, and LW was willing to discuss further amendments provided this did not delay issue for more than 2 weeks. It was important that both parties felt comfortable with the final content.

It was agreed that the covering letter, which would go to haematologists, must encourage discussion with end users/hospital transfusion committees/blood product budget holders. The way in which queries arising out of distribution of the leaflet were handled was important, and that Octapharma should have some input into the replies.

LW had sought clarification from the MCA on licensing for neonates. Exchange transfusion would not be listed as a specific indication, but would not be listed as a contraindication either. MCA had not expressed any other views on its other possible uses in neonates. The final information leaflet should also take a neutral position.
Action: Octapharma to discuss with LW possible amendments to information leaflet, and LW to redraft.
LW to draft covering letter and make available to Octapharma.
LW to discuss future queries with Octapharma.
Octapharma will seek permission from MCA to hold an educational meeting on Octaplas prior to launch.

4. Proposed timetable for implementation.

KL presented a possible timetable for SDFFP implementation. This assumed licensing by the end of the year. However, KL agreed that if there had to be a delay of a few weeks between licensing and availability of SDFFP from UK plasma, then Octapharma would NOT market SDFFP from other sources in the interval.

The additional information required by the MCA related to coagulation factor activation, and validation of anti-HAV/HAV PCR testing of final pools.
Octapharma would need BPL's plasma master file for submission to MCA.
Action: TS to provide plasma master file to Octapharma. /delayed ∵ octapharma legal people amending BPL confidentiality agreement

The timetable as presented proposed 10 batches of 380 litres for initial treatment. LW pointed out that no decision could be taken yet on how much would be needed, but that it was unlikely that any emphasis could be given to group AB. The size of the first lot to be shipped would have a temporary knock on effect on plasma supply to BPL.

From Octapharma's point of view, the minimum which could be accepted initially was 1 batch; there was no maximum. Octapharma would need no more than 2 weeks' notice as to the volume of the first batch, when the documentation would have to be available.

It would be necessary for Octapharma (BG) to carry out a supplier audit of centres providing plasma.

Action: NBS (Implementation group) to provide estimated volumes
: Terry Snape to find out requirements of other UKTransfusion Services
:David Wesley/Barbara Glantschnig to discuss documentation
: LW to inform supplying centres re audit visit

5. Technical details (see also attached 'question and answer' sheet).

5.1 Start plasma

Volume/pack - any volume between 100mls and 900mls would be acceptable.
Anti-hepatitis B core testing would NOT be required, as stated at Qu 1.
The box should show blood group and lot number.

5.2 Final product

Each pool would be tested for total protein, fibrinogen, factors V and VIII and APTT.
Anti-HAV also as described, but not anti-B19.
Packs would be issued double wrapped.
The shelf life would be 12 months.

The label should reflect the joint 'ownership' of the product - it would be called Octaplas, but carry both Octapharma and NBS logos. Black and white group labelling was possible. There would be both eyereadable and bar coded versions of the batch number.
Action: LW to investigate how hospital computers would handle a batched product with a blood group.

6. Distribution/price

TS/DW agreed that ideally BPL would be involved in distribution, but would prefer only to distribute to 1 site/zone and at infrequent intervals.
Action: LW to discuss with implementation group.

B Savery said that a national price would be preferable. Octapharma's indicative price was £20/200mls on top of FFP price. They may also need to be a handling charge to cover BPL's costs.

7. Post-donation information/sample archiving

The system for handling both post-donation information and donors who sero-converted for viral markers would have to satisfy the requirements of both Octapharma and the MCA. In the latter case, MCA was informed, and a decision to withdraw a pool/recall product taken, depending on the PCR status of the archive.
A clear system would have to be established which defined responsibilities and communication lines.
Action:Octapharma to provide a list of criteria for informing them about post-donation information.
: LW to provide details of current system for plasma sent to BPL.

Date of next meeting 19th September 1997 1pm NBA HQ, Watford.