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Copy: Mr Pudlo Ca-OPU2

BPL SUBMISSION

1. I discussed briefly with Mr Pudlo prior to his minute to you of earlier today. My contributions are as follows.

Para 15 (e)

2. The reasons for rejection of the alliance with a commercial partner have not changed. The plasma that would be brought in to fractionate would still be paid plasma together with its political connotations. MCA assure us that it should be possible to separate paid plasma from UK unpaid plasma to prevent contamination, but this would be extremely difficult to explain to the public who would also be anxious about contamination. Also the presentation of this option as part way to privatisation would be extremely difficult to refute, particularly if the proportion of plasma being processed for the NBA were smaller than 50% in the longer term. The situation as regards ALT testing has, if anything, changed against the introduction of this. Two factors that need to be considered is that the FDA no longer insists upon ALT testing as well as the finding that ALT testing does not differentiate between donors positive and negative for the newly discovered hepatitis G virus.

Appendix 2, para 8, ALT Testing

3. ALT is an enzyme produced by the liver. Its level is increased where there is damage to the liver. Prior to the existence of a specific test for hepatitis C, some countries introduced ALT testing as a surrogate test for hepatitis C (then known as non-A, non-B hepatitis - NANB hepatitis). Some of the early studies suggested that this was a helpful test, although following the introduction of this test in the US, there was no reduction in the amount of NANB hepatitis transmission by blood. In the late 1980s DH commissioned an investigation of the use of ALT, as well as another test (anti-HBc) on a sample of the UK donor population. These results showed no correlation between NANB hepatitis and a raised ALT. Many individuals with a raised ALT had either recent increased alcohol intake or were obese. For these reasons ALT were never introduced into the UK Blood Transfusion Service.

4. In 1989 a test was discovered for hepatitis C, which was improved over the next two years prior to routine introduction into the UK Blood Transfusion Service in

September 1991. There was an opportunity at that time for those countries which were using ALT testing to abandon it, since the primary reason for doing the test had now gone away. However, it is very difficult to stop doing a test ostensibly for the safety of blood, whereas it is much easier to introduce new tests. This is primarily because of the public perception. Technical experts from Europe and the US found difficulty in justifying the continued use of ALT, and some frankly admitted that the retention was purely for public consumption. In early 1995 the FDA decided to stop insisting on ALT testing, if a donor were tested and found to have a high ALT, it was suggested that it would be appropriate not to use the blood from that donation.

5. BPL has asked for ALT testing because several European countries, in particular Germany, insist upon this test. This is despite the fact that blood products are governed in the EC by a Directive, EEC/89/381, and the guidelines emanating from this do not state that ALT testing is a requirement. Although the German action can be considered as a restriction of the free market, no one is prepared to take the Germans to the European Court. The insistence on ALT testing is not claimed under a public health derogation.

6. Additionally, there was the requirement that the same fractionation plant could not process ALT tested and non-ALT tested plasma if it wanted a licence at the time when the FDA insisted upon ALT testing.

7. The MSBT have considered ALT testing in late 1994, and they concluded that ALT testing was not justified on grounds of safety: The NBA accept that testing for ALT is purely for commercial reasons, and seem to believe that this would be an acceptable way of presenting it to the public.

8. The problems with the introduction of ALT testing are not just the actual cost of the test. This would lead to the exclusion of some blood donors, who would need to be told that although they were probably healthy their blood could not be used. Such action could, itself lead to the problems. Additionally, these donors would need to be replaced. The NBA produced a report in September 1994 which estimated that the annual cost of introducing ALT testing, staff, test kits, replacement of donors would amount of £1.06m per annun.

Appendix 3, para 4, Move to Central Funding

9. Any reduction in the price of NHS Factor VIII could be looked upon by clinicians as a device to prevent the use of recombinant Factor VIII and protect BPL. The Department would run the risk of being accused of promoting a "less safe product". The manufacturers of other plasma derived product would also complain, saying that this was a denial of clinical freedom, an excuse which the Department has used for many years to justify the sale of commercial blood products in England.

Appendix 5, just a brief note

10. One could summarise the situation in the EU as follows. Although all countries

are officially committed to self-sufficiency on the basis of unpaid donation, there is some disagreement about whether the self-sufficiency should be within countries or across the whole of the EU. Most countries have sufficient red cells and platelets with the marked exception of Greece, which by virtue of its population with thalassaemia who require regular blood transfusions, imports red cells primarily from Switzerland. There is relatively little export of red cells outside the EU, the exception being the Netherlands who export some to the New York Blood Centre. The situation with Factor VIII concentrate is different however. There are several countries which try to be self-sufficient, and have large collections of blood. This group includes Denmark, Belgium, France, Luxembourg and the Netherlands. France's blood donations have dropped significantly since the AIDS scandal and in 1993 imported 15.5 million units. France has also tried to ban importation on the basis of donations from unpaid donors being safer. The other countries in this group tend to only import small amounts, primarily if these are specialised products which they do not have available, or if there is some local problem with production or safety. At the other extreme there is Germany, Italy and Spain which import large amounts of plasma as well as some finished product. Some of their imported plasma is then re-exported as finished product. The UK probably is the only country which has a totally free market.

11. Happy to discuss.

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