Reference H1B23/04 68

Mr Wormald
Mr Harley
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Dr Harris
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for information

SCHEME FOR THE FUTURE PRODUCTION OF BLOOD PRODUCTS IN THE UK

Dr Harris has suggested that you might care to have a copy of the attached scheme for the future production of blood products in the UK. It represents my preliminary thoughts on a complex matter which has been preoccupying you for a considerable time and I do not doubt that this scheme, or something similar, is but one amongst the many options which you may have been considering.

The salient features of the scheme should be clear from the flow chart but I should like to add a brief commentary:

1. If it is accepted that production at BPL should continue for the present, then stop-gap or an appropriate modification of it should be implemented forthwith, both to satisfy the Medicines Inspectors and to increase production.

2. With agreement from Ministers as necessary (presumably Mr Harley's paper will provide the impetus for this) we should enter into immediate and very searching negotiations with likely commercial contenders for UK fractionation. There may well be a sticking point about the margin of profit which the DHSS and the companies each consider acceptable! It may, therefore, become apparent at an early stage in these negotiations that the commercial option is less open or less attractive than it currently appears.

There would also, at present, seem to be at least 2 different types of commercial fractionating venture possible. One is for commerce effectively to take over from BPL and fractionate NBTS plasma, the cost of product to reflect the free donations. The other, which is what Immuno Ltd wishes to do, is to set up 3-4 plasmapheresis centres for paid donors and to fractionate, in a purpose-built UK plant, UK-derived and foreign plasma for the export market. It seems to me that there are signal advantages in having both types of operation in the UK. Firstly, although Immuno would be largely fractionating for export purposes, if the company fractionating NBTS plasma (say, for argument, Kabi) were to cause difficulties, there would then be the sanction of transferring the NBTS plasma to Immuno. Secondly, it is clear that the cost per unit of a blood product derived from freely-donated plasma should be less than that derived from paid donors, all other things being equal. By having the two types of operation within the UK, we would have an in-built yardstick by which the efficiency and the profit margin of the company fractionating NBTS plasma might be monitored.

3. What I see as an essential NHS fallback capacity in this scheme would be provided by the suitably modified operation of Liberton.

4. If the UK is to attempt self-sufficiency in blood product manufacture (by commercial or non-commercial means), it is clear that the output and quality of the plasma from RTCs must be substantially improved. Indeed, some estimates for the future requirements for factor VIII and albumin are so high that, even with a much increased plasma yield from the NBTS, a system of plasmapheresis might be required to make up for the shortfall in the amount of plasma required.

In order to separate the issues relating to the development of UK blood products manufacture from the problems relating to possible reorganisation of the NBTS, I offer the following observation: with suitable phasing, so that stop-gap may be completed, the production of cryoprecipitate at RTCs should cease and the donations which would otherwise have been used for cryoprecipitate production should be sent, in single packs, to the 'up-graded' BPL for processing. Thus, without any need to await complex administrative changes in the NBTS, both the quantity and quality of the plasma going to BPL would be improved with a corresponding significant improvement in yield of factor VIII per unit of plasma.

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