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SofS

From: Charles Lister PH6

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cc: see attached

US PLASMA SHORTAGE: IMPACT ON BIO PRODUCTS LABORATORY/ SUPPLY OF BLOOD PRODUCTS TO THE NHS

Issue

1. We need to take immediate action to secure the supply of blood products for the NHS.
2. The NHS-owned Bio Products Laboratory (BPL) relies on imports of US plasma to make blood products for the NHS. Key products are intravenous immunoglobulin for immune suppressed patients and clotting factors for haemophiliacs (about half and one third of NHS usage respectively). There is, however, not enough US plasma being collected to meet the needs of the blood products industry worldwide and increasing the amount collected will take years to achieve.
3. This has precipitated a race by the commercial blood product manufacturers to acquire all the independent plasma suppliers in the US for their own exclusive use. This is happening at enormous speed and will cut off BPL's supply of plasma and cause a shortage of key blood products for NHS patients unless we take immediate action and pursue the same aggressive policy as the commercial sector.
4. This submission, which has been agreed with Pat Troop, explains the background to the plasma supply situation, discusses the limited options available to ensure continued supplies of blood products for NHS patients and seeks your agreement to proposed action.

Timing

5. Immediate. We have only one option available at the moment to secure sufficient plasma supplies for BPL and we are in direct competition for this with the multinationals.
6. Deals being offered to us by plasma suppliers are being offered simultaneously to the multinationals. We have therefore been pushed into a purchasing race. For example, we met one supplier yesterday morning only to discover that the deal we thought was on offer had been snapped up by Bayer in the 12 hours prior to the meeting.

Background

7. Annex 1 explains why we are in this situation.

Options

8. Our key strategic requirements are to provide a secure supply of blood products for the UK population. A number of options have been explored, which are set out in Annex 2.

In summary these are:

- secure a plasma supply for BPL
- place BPL in a PPP with a commercial producer that has secured its plasma supplies;
- obtain plasma from elsewhere in Europe or the rest of the world;
- go back immediately to using UK plasma;
- wind up BPL and rely on the purchase of products from commercial suppliers to meet the needs of NHS patients.

9. From these options, we consider the most reliable way of securing a long term supply would be to secure the long term future for BPL, which in turn requires a guaranteed plasma supply.

Therefore our key objectives would be:

- obtain a secure plasma supply for BPL from a BSE/vCJD free country to ensure a continued secure supply of blood products to the NHS;
- enable BPL to continue manufacturing at its current levels with the ability to step up production in the future in line with its business plan.
- make BPL a more attractive proposition to potential PPP partners.

10. The most viable option to achieve these aims and allow BPL to remain in business beyond 2002/03, is to purchase a US plasma supplier for BPL. BPL has contracts with three plasma suppliers - Sera Tec, Nabi and DCI – which come to an end at various stages in 2002/2003. Sera Tec and Nabi, BPL's main suppliers, have recently been acquired as part of the current purchasing frenzy and will not renew their contracts with BPL. The only contract remaining is with DCI which is also a target for take-over and is currently in discussion with potential corporate purchasers.

Securing the plasma supply from DCI

11. DCI is the largest remaining independent supplier and the only one that can meet all, or almost all, BPL's raw material needs at BPL's existing manufacturing level. We have held exploratory talks with DCI who would be willing to consider a partnership arrangement with BPL, although they are also talking in parallel to the multinationals.

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12. The only deal DCI are prepared to offer is a two stage process that would involve us purchasing:

- (i) a minority shareholding in the company within the next 6 months to guarantee plasma supplies to BPL;
- (ii) the remaining shares in the next 5-7 years at a price agreed through a formula designed when the minority shareholding is sold.

Under this arrangement, the present owners of the company would retain control for the next 5-7 years during which they would seek to double the 20 centres currently operated by DCI.

13. If we succeed in buying into DCI, this would form part of a proposed PPP package (the business case for which is currently being assessed by DH finance colleagues prior to going to Ministers). The current strategy for BPL is to place it in a PPP well within the next 5 years with a commercial partner that has the capacity to manage a US operation.

Cost

14. The acquisition of DCI would require a significant financial commitment. A valuation of the company is not possible at this stage, but a range of \$70-80m (£45-52m) would be a reasonable estimate. The purchase of the minority shareholding would therefore be in the \$20-25m (£13-16m) range. The total purchase price could double to around \$140-\$160m (£90-£104m) if DCI successfully completes its expansion plan.

15. As well as finding the capital for the initial purchase this financial year, we would need to appoint specialist consultants and lawyers to assist in the acquisition. This could cost an additional £1m revenue this financial year.

16. We have discussed the finance aspects with Richard Douglas who, subject to your views, has acknowledged the need to find the money and to raise the issue with Treasury.

Vires

17. It is unclear at this stage whether Government has the legal powers to make such a purchase. Our lawyers are currently working on finding a way round this.

Other Options for obtaining a plasma supply

18. There are other options to obtain plasma supplies that we are actively pursuing but none would come close to meeting BPL's annual plasma need:

- (i) one supplier, Plasma Care, is offering to build five new plasma collection centres over 5 years to supply BPL in exchange for loan guarantees from the Department. The guarantees would be at the level of roughly \$1.5m per centre.

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This deal is again being offered to others and will only remain open to us if we grab it first;

(ii) another supplier, Nabi, may be willing to set up new centres for BPL if we put up the purchase price. BPL is currently establishing whether this offer is open or not.

19. BPL are continuing to follow up all potential deals as they arise.

Conclusion

20. Because of concerns that vCJD may be transmissible through blood we have no choice but to use US plasma as a raw material for the products manufactured by BPL. Immediate action is therefore needed to secure supplies.

21. Paradoxically, US plasma is in short supply partly because of the United States' own vCJD risk reduction measures. And BPL is being squeezed out of the market because as a public body it cannot, unlike other manufacturers, raise capital to buy its own supplier.

22. Although there are hopes that BPL left to its own devices can secure some plasma supplies, the most optimistic assumptions still leave it far short of its needs. We are therefore left, essentially, with two options:

(i) buy an existing US plasma supplier (DCI) for BPL to ensure continuity of supply with a mind to including it, with BPL, in a PPP package;

(ii) wind up BPL and rely on the market to supply the NHS in England & Wales with all its blood product requirements.

23. We recommend the first of these options on the grounds that, in the medium to long term, this secures greatest value for the NHS and does not entail the very real risks of option (ii), ie price rises and product shortages. If you agree, we propose that BPL give DCI an immediate indication of interest so that discussions can commence whilst the legal issues are resolved, the finances are identified and Treasury approval is obtained.

24. As the deal with DCI may fall through for a variety of reasons – eg they may be purchased by one of BPL's competitors – we also recommend that BPL pursue negotiations with the companies offering the deals set out at para 18 above, subject to the same caveats as above.

25. We are also developing contingency plans in case none of these deals are successful and BPL is forced to stop production during 2003/04.

26. Are you content for us to proceed on this basis?

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SECURING US PLASMA SUPPLIES: BACKGROUND

1. Three years ago we stopped using plasma from UK donors in the manufacture of blood products such as clotting factors and immunoglobulins. This was a vCJD risk reduction measure recommended by SEAC and MCA. We will not be able to return to using UK plasma for the foreseeable future until a reliable vCJD screening test is developed.

2. NHS Trusts purchase blood products from BPL and from the commercial sector. But, unlike commercial companies, BPL is required to supply the NHS. BPL therefore provides an important stop-gap for the NHS in the event of product shortages which occur fairly frequently in this sector.

3. The structure of BPL is under review with a PPP the favoured option. The BPL business plan is driven by an increase in its production of plasma products – it is currently operating at 50% of its capacity - which in turn requires a larger input of raw plasma.

4. BPL imports plasma - its raw material - from the US, where there have been no reported cases of BSE or vCJD. We are the only country that relies exclusively on US plasma which places us in a uniquely vulnerable position. However, the US plasma market has destabilised rapidly, probably due to a number of factors:

- a reduction in plasma collection caused partly by improvements in the US economy (fewer people selling their plasma) and the introduction of bans on donors who have spent time in the UK and the rest of Europe;
- an increase in the capacity of commercial blood product manufacturers following a series of recent mergers and acquisitions;
- the entry into the US plasma market of the UK and increased demand for US plasma from elsewhere in Europe;
- the current world shortage of synthetic clotting factors for haemophiliacs which has increased the usage of plasma derived products.

5. This has resulted in a scramble for control of the plasma suppliers by BPL's commercial competitors and a rise in prices. Securing plasma supplies has become a key objective of blood product manufacturers worldwide and, with European plasma increasingly seen as unacceptable by the US authorities because of the perceived vCJD risk, all the pressure is on the US market. Other potential sources of plasma are either too small – eg Canada or Australia – or too virally contaminated – Eastern Europe and the Third World.

6. BPL has contracts with three plasma suppliers - Sera Tec, Nabi and DCI – which come to an end at various stages in 2002/2003. Sera Tec and Nabi, BPL's main suppliers, have recently been acquired as part of the current purchasing frenzy and

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will not renew their contracts with BPL. The only contract remaining is with DCI which, in the current climate, is also a target for take-over.

7. The situation is therefore very precarious with BPL facing shutdown in 2003/04 if it cannot establish new sources of plasma. Without some form of immediate Government intervention the chances of BPL staying in business seem remote.

SECURING US PLASMA SUPPLIES: OTHER OPTIONS**(i) *seek alternative contracts with US plasma suppliers;***

The shortage of plasma collection means that this is a high-risk option. Potentially the NHS could use its purchasing power to try to leverage a deal with a large multinational but this is likely to meet considerable resistance. The market information available is that all blood product manufacturers are trying to secure their supplies and there is not likely to be any surplus that BPL could buy. This option could result in BPL paying inflated prices to secure plasma and with no guarantee of security.

(ii) *place BPL in a PPP with a blood products manufacturer that has secured sufficient US plasma supplies to run both its business and BPL's.*

This is an option we have been working on for some time following a request by the Chief Secretary to review future management arrangements for BPL. Because of the restrictions placed on BPL as a public sector body, including its lack of access to venture capital, it cannot survive in the commercial market as a purely publicly owned body without substantial injections of cash from DH central funds. As part of a PPP it has the potential to be profitable.

An outline business case setting out the PPP options is currently with Finance colleagues and proposals will be submitted to Ministers in the near future. However, it would be far too risky to rely on this as a solution to BPL's plasma supply problems:

- there are only three blood products manufacturers with secure plasma supplies who might be interested in a partnership and market information suggests that they will have insufficient supplies to meet BPL's needs as well;
- we do not, in any case, have time to implement this option;
- BPL as a factory without access to raw materials would be less attractive to a potential partner than one with secure plasma supplies.

(iii) *look for plasma supplies elsewhere in Europe or the rest of the world*

There are no surplus supplies in Europe which in any case is considered too risky given that cases of BSE and vCJD are emerging in a number of countries. European plasma is increasingly being seen as undesirable by the US and even by some developing countries. Indeed, the US FDA is considering a requirement on manufacturers supplying blood products to the US to have separate production lines for US and European plasma.

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The fact that BPL is the only European manufacturer using US plasma exclusively puts it at a distinct commercial advantage in developing its export potential, essential if it is to operate at full capacity.

Other potential sources – Canada and Australasia – do not have enough plasma to meet their own domestic needs. In developing countries – eg China – plasma collection is unregulated and would not meet our stringent safety and quality requirements.

(iv) *go back immediately to using UK donor plasma*

This would only become a viable option once a reliable vCJD screening test has been developed. This is likely to be at least 2 years away and probably much longer.

(v) *wind BPL up and rely on the purchase of products from commercial suppliers to meet the needs of NHS patients.*

Winding up BPL would leave a gap in supplies to the NHS of two major products and/or lead to other suppliers raising their prices:

- *intravenous immunoglobulin (IVIG)* for the treatment of immune suppressed patients. BPL has a market share in excess of 50%. This product has been subject to worldwide shortages in the past and, most recently, in January this year when Novartis reduced substantially its supplies to the UK. Even if the NHS can be supplied by other manufacturers - and this is by no means certain - the demise of BPL would make the UK more vulnerable to future product shortages

It is also highly likely that the withdrawal of BPL from the market would see rises in the price of IVIG. The recent shortage led to a 50% increase in price. If this were to be repeated the extra cost to the NHS in England & Wales would be £17m a year.

- *Factor VIII* for the treatment of patients with haemophilia A. BPL currently supplies around one third of the NHS market. The NHS need for these products will decline if Ministers decide to fund the provision of synthetic clotting factors (a SR 2002 bid is being developed to achieve this). However, this would have to be phased in over 3 to 4 years so the need for plasma derived Factor VIII will continue, albeit at a reducing level, until then. The risk of shortages of these products in the UK would therefore increase.

Again, withdrawal of BPL would enable other suppliers to push prices higher. For example a 5p rise from 28-30p/iu to 33-35p/iu would cost the NHS in England and Wales an extra £8m a year.

Other BPL products could probably be replaced by other suppliers although some prices rises for Factor IX and Anti-D are possible, say by £1m a year
In addition closure would entail:

- the loss of 500 jobs and wind up costs of around £15m;

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- the payment of around £6m for defaulting on contracts;
- loss of value of tens of millions of pounds when the plant is sold off.

This would be a high risk strategy in terms of security of supply of key blood products to the NHS. The blood product industry is very highly regulated and a number of suppliers, particularly in the US, have been shut down for prolonged periods for failing to meet the exacting standards of the regulators. Because there are only a handful of blood product manufacturers worldwide, this leaves all countries vulnerable to shortages particularly if they do not have their own domestic manufacturing capability. Although Scotland has its own blood product manufacturer, this is too small to meet the needs of the entire UK in such a situation. Were this option to be pursued, we would need a clear exit plan for BPL and the involvement of PASA in securing new contracts.

This option would also lose money for the NHS in the medium to long term both because it would allow the remaining suppliers to raise prices but also because, properly resourced in a PPP arrangement, BPL has the potential to be a valuable asset and a source of income. It would also be a politically controversial move for all the reasons mentioned above.



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