Lady Hayman

From: Charles Lister HSD1
Date: 20 July 1999

cc: see attached.

REVIEW OF UK BLOOD PRODUCTS MANUFACTURING

Issue

1. As you will recall, we have been working since last Autumn with Scottish Executive Health Department (SEHD) and Treasury officials on a review of blood products manufacturing in the UK, the aim of which is to ensure value for money in the use of UK fractionation capacity and a reasonable return on public investment. This has involved us in considering options for the future of the two NHS-owned plasma fractionators – the Bio Products Laboratory (BPL) and the Edinburgh-based Protein Fractionation Centre (PFC).

2. Before we proceed any further, we would welcome your views on our emerging conclusions and your guidance on which options you would like us to explore in greater depth. The central question is whether we should explore options that would involve significant private sector investment in BPL

3. This submission has been agreed with Scottish Executive and Treasury officials. Scottish Executive officials are submitting a parallel submission to Susan Deacon MSP.

Recommendation

4. We recommend that you agree to consider options that require private sector investment in BPL and that external consultants be contracted to carry out market analysis and develop the options further.

Background

<u>The Review</u>

5. The review was requested by the then Chief Secretary in a letter to the Secretary of State of 24 February 1998. In giving his agreement to the use of non-UK plasma for the manufacture of blood products, the Chief Secretary asked Secretary of State to:

> "carry out a full study of the potential scope for savings in the longer term from restructuring the provision of blood products for the GB NHS. I understand that both the Bio Products Laboratory and its Scottish counterpart are working below capacity".

6. The terms of reference for the review were later modified at the request of Scottish Ministers to focus on options for BPL "taking account of the existence of

PFC". These are at Annex A. This submission concentrates therefore on options for the future of BPL.

7. The Secretary of State wrote to Stephen Byers on 6 November (letter attached at Annex B) to inform him of our plans for the review. However, since then, we have agreed with Treasury and Scottish Executive officials to extend the timetable because of the time required to review the options thoroughly and to take account of the establishment of the Scottish Parliament and the National Assembly for Wales. Treasury officials are, however, keen for us to complete the review as quickly as possible.

BPL & PFC

8. BPL is part of the National Blood Authority and supplies plasma-based products (immunoglobulin, albumin, Factor VIII etc) to the NHS in England and Wales. PFC is part of the Scottish National Blood Transfusion Service and provides a similar range of products to the NHS in Scotland and Northern Ireland. Both were originally set up in 1950 to meet a government commitment to self-sufficiency in plasma fractionation and manufacture of plasma products for the NHS. There was also a deliberate policy to have two fractionation plants in operation in the UK in case production had to stop at one of them for whatever reason.

9. BPL's total budget in 1999/2000 (measured as total costs, since these exceed revenues – see para 11 below) is expected to be around £68m. PFC's total costs this year should be around £11m. At present, BPL employs around 500 staff and PFC around 120.

10. Since the introduction of charges to the NHS for blood products in 1989/90, BPL has operated on a commercial basis, in competition with other commercial manufacturers. National self-sufficiency in products is therefore no longer a primary objective for the National Blood Service, and BPL has lost some of the market for its main products in England and Wales. It now has around 95% of the market for albumin, 60% of the market for plasma-derived coagulation factors and 20% of the market for intravenous immunoglobulin.

11. At market prices BPL has been unable to cover its costs. It has made a financial loss and received a subsidy from the Department every year except 1994/5 from funding which would otherwise go direct to health authorities (around £15m in the current financial year) and is forecasting continuing losses until 2002/03. In addition, the Department provides BPL with capital funding of on average around £2-3m pa. The full cost to the NHS of BPL's products has therefore been greater than their market prices. Set against this is the argument that the existence of a large publicly owned plasma fractionator in England has contributed greatly to keeping blood product prices lower here than in the rest of Europe, although it has not been possible to prove this either way.

12. PFC is centrally funded by the Scottish Executive. It does not charge NHS users for its products in Scotland and hence has a virtual monopoly of the NHS market. A natural consequence of this is higher usage rates among Scottish clinicians for some PFC products such as albumin. PFC also sell some surplus products to the NHS in England at cost recovery.

13. BPL is permitted to use any surplus capacity, after supplying the NHS, to produce products for export. PFC are discussing plans to do likewise with officials in the Scottish Executive. A declining market for plasma products in the UK (see para 14 below) means that this is becoming an increasingly important element of their business.

14. The main factors affecting the performance of BPL and PFC are:

- *the increased costs of importing plasma because of the theoretical risk of nvCJD* - BPL and PFC have now stopped processing plasma from UK blood donations. In the case of BPL, this has raised its main raw material costs by around 40%. If and when it becomes possible to test blood donors for *nv*CJD, use of UK plasma will resume, although this may not be for some years yet;

- *improvements in technology (recombinant blood products) and reductions in the demand for plasma products (albumin) by the NHS and the introduction of competition* have left the UK overall with considerable excess fractionation capacity:

  - BPL's fractionation capacity is around 800 tonnes per annum (although it has the potential to expand to 1000 tonnes) but its throughput this year will be only around 440 tonnes (300 for the NHS, 140 for export);

  - PFC's fractionation capacity is around 100 tonnes per annum, with some built-in scope for increasing production by introduction of extra shifts. Most of this capacity is currently used in supplying the NHS. This is expected to rise to 150 tonnes per annum in 1999 to accommodate a commercial contract to fractionate Taiwanese product for Taiwan;

  Looking at the UK as a whole, out of a total fractionation capacity of 900-950 tonnes per annum, only around 400 tonnes is now required to meet the UK NHS demand for BPL's and PFC's products. By 2001/02 this could drop to a maximum of only 300 tonnes per annum (200 tonnes for the NHS in England and Wales; 100 tonnes for the NHS in Scotland and Northern Ireland), due to a combination of three factors: the reduction in NHS demand for albumin, the increasing availability of recombinant alternatives to plasma-derived Factor VIII and Factor IX (which neither BPL nor PFC produce), and forecast improvements in yields

- *the very high fixed costs associated with plasma fractionation technology* which means that only large-scale production is commercially viable (in BPL's case, around 40% of their costs are fixed for reasonable changes in throughput).

Consequently there has been significant consolidation in the plasma fractionation industry worldwide, and some of BPL's competitor companies are now operating plants with capacities of up to 2,000 tonnes per annum. BPL estimates that the optimal throughput for its plant is now around 1,000 tonnes of plasma per annum, more than twice the current level.

Options

15. There are various options for the future of BPL, the advantages and disadvantages of which are discussed below.

The options are:

A. *The status quo*: wholly public ownership as now with BPL part of the NBA.

B. *Keep BPL as a publicly owned body but change its status to that of a trading fund.*

C. *A form of public/private partnership*. There are two main forms to consider:

(a) sale of the BPL plant with a contract to provide blood products to the NHS at an agreed price for, say, the next 10 years (using UK plasma when possible). The price would be reviewed periodically through a system of benchmarking against world prices. Under this option it would be possible for the NHS to buy back the plant at the market price at the end of the contract;

(b) a joint venture, where the government would contribute the plant and a partner would provide funding for further investment;

D. *Privatisation.*: sale of BPL's plant to the highest bidder and a competitively-awarded contract to provide blood products to the NHS in England and Wales with either an expanded PFC or another company.

E. *Supply the whole of the UK NHS from PFC in Scotland and sell BPL to the private sector*

Option A, Status Quo: In order to break even, BPL needs to put increasing emphasis on acquiring contracts to manufacture products for export. This requires acceptance on our part that more than 50% of BPL's business, as a NHS body, would be devoted to producing product for export (it could be argued that such income generation would be to the benefit of the NHS, although this is something we might need to clear with the Audit Commission). Even so, unless the Department were prepared to provide BPL with the necessary central funding, it would suffer from shortage of capital investment and become non-viable in the medium term. BPL is forecasting capital needs of around £6 million per annum over the next 5 years and beyond. At present, the Department provides less than half this amount. There is also the risk

that if sufficient export work is not forthcoming or contracts not renewed, a central revenue subsidy from the Department would continue to be needed.

Option B, Trading Fund: This would involve separating BPL from the NBA and making it directly accountable to the Department. As a Trading Fund, BPL would be able to keep any surpluses it made as long as they were ploughed back into the business. It would also be able to borrow commercially subject to Treasury agreement. However, any loses made by BPL could not be borne on the Vote as they are now. As BPL are forecasting loses each year until 2002/03, even with export contracts in place - and, on a worst case scenario, could still be making loses in 5 years time - this has no immediate attractions.

Option C/D: A public/private partnership or full privatisation: Private sector investment in BPL could bring extra volume (ie a bigger customer base and more plasma fractionation contracts), expertise and experience in exporting products, and additional capital. There are a number of options available to us, ranging from PFI deals to outright privatisation. However, these would need further work by external consultants with skills we do not have in house. Central to any such arrangement would be the need to ensure security of supply of high-quality, competitively-priced products for the NHS. This could be achieved by means of a fractionation contract for supply of products, perhaps for 10 years, which would allow for a return to UK plasma if and when that becomes possible.

Option E: Supply the whole of the NHS from PFC in Scotland: Given its currently small capacity, PFC would not be able to meet UK NHS demand without an initial capital investment of at least £5m. The practical arrangements would be fairly straightforward – the NBA could purchase products from PFC under contract and sell to the NHS in England and Wales (a similar arrangement currently operates between PFC and Northern Ireland).
Such an arrangement would of course leave us with an unused plant at BPL, which would have to be sold to the private sector. We have heard anecdotally that there are commercial fractionators who might be interested in purchasing BPL, but this would need to be investigated further. The income from such a sale would be substantial (one estimate values BPL at £70m) and would more than offset the capital investment needed to expand PFC.

This option would still leave us with the kind of financial risk described at Option A, although the fact that even an expanded PFC would be much smaller than BPL would tend to reduce this risk. Ongoing capital investment would also be needed, but this again would be smaller than at present and be shared with Scotland, as would the costs of R&D.

A factor that would tend to increase the financial risk inherent in this option is that, although BPL and PFC produce essentially the same product range (albumin, immunoglobulin etc) they do so using different processes, using either their own patented technology or technologies purchased from commercial companies. Although BPL and PFC's products should be interchangeable as far as patient treatment is concerned, some clinicians develop a "brand loyalty". There is

therefore a risk that in the absence of BPL they would choose to purchase from commercial competitors rather than PFC, leaving some of PFC's additional capacity unused.

Compared to options C(a) and D, where the contract to supply the NHS in England and Wales would be awarded competitively, this option could also lead to higher prices being paid for plasma products. Like the contracting options, therefore, any arrangement with PFC under option E would need to be for a limited time and would include periodic price reviews with reference to world prices.

16. We have also considered whether PFC might close and pass its business to BPL. However this would not be a complete solution to the problems described above as BPL would still have substantial over capacity. We also recognise that, in the light of Scottish devolution, this might not be a viable option politically and would, in any case, go beyond the terms of reference for the review.

Discussion

17. BPL is operating in a declining NHS market for its products, with increased raw material costs and an under-utilised, high-cost plant. Unlike PFC, it is also competing for this declining market with commercial companies which do not face the restrictions imposed on BPL as part of a SHA. For example, BPL's ability to compete is progressively being restricted by its limited access to capital funding for investment in plant, equipment and research and development. Any such funding has to come at present from the Department, and is therefore liable to be restricted for reasons which have nothing to do with the commercial needs of BPL.

18. The only way in which BPL can utilise its excess capacity is to negotiate contracts to manufacture products for export. PFC have entered into a contract to fractionate product and transfer technology to Taiwan, and BPL are currently negotiating a substantial contract to manufacture a new plasma-based product for sale in the US only (the subject of a forthcoming submission). BPL estimates that if it is to break even by 2002/03 it will need to earn over half of its sales revenue from exports, an increasingly anomalous position for a NHS body. It also has relatively little expertise at present in export marketing.

19. In the medium term – with a sharp decline in domestic demand for plasma products and the large economies of scale required for a fractionation plant to be viable - the case for the NHS owning any plasma fractionation capacity will become less easy to sustain on economic grounds. Any decisions made now need to take this into account. There is a judgement to be made about the stage in the process at which the benefits of NHS ownership begin to be outweighed by the costs.

Conclusion

20. It seems clear that retaining the status quo for BPL is not a option on its own. Even if it were to remain part of the NHS, BPL would have to increase its

reliance on exports considerably in order to survive and probably extend its range of products. There would also need to be a firm commitment from the Department on capital investment and continuing subsidies. The Trading Fund option is attractive in that it would give BPL more flexibility in retaining surpluses and raising capital, but is only a viable proposition if it is trading healthily, which may not be the case for some years. In any case, the industry is changing so fast that a further review would probably be required in 2-3 years time if BPL remains in NHS ownership.

21. We do not have the necessary expertise within the Department to assess the options available to us for private sector investment in BPL. We would therefore welcome your views on whether you are content for us to employ external consultants on a confidential basis to assess these options. If so, a detailed specification for this work could be drawn up and agreed with you, with a view to commissioning a report by the Autumn. Depending on the consultants employed and the time needed to complete this work, this could cost in the region of £40-50,000. We plan to find this money from the NBA's existing 1999/2000 cash limits as an efficiency saving.

22. If you are content, we would also explore further the scope for extending BPL's freedom of operation whilst remaining NHS owned (eg through a trading fund), and for supplying the UK NHS from PFC, so that we can present you with a full range of costed options later in the year.

Next Steps

23. As this is a joint review with the Scottish Executive, we propose that the next stage should be an exchange of letters with Susan Deacon to reach an agreed way forward. This joint decision can then be communicated to the Chief Secretary and to Welsh and Northern Irish Ministers. We will draft an initial letter for you to send to Susan Deacon when you have decided how you wish to proceed.

24. If you would find it helpful, we would be happy to arrange a briefing meeting with colleagues from EOR and Finance to discuss the proposals in this submission.

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Copies:

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Mr Palmer Scottish Executive
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ANNEX A

REVIEW OF BPL'S BLOOD PRODUCTS MANUFACTURING WITH REFERENCE TO PFC: TERMS OF REFERENCE

To identify and assess future options for the operation of the Bio-Products Laboratory (BPL) taking account of:

- the existence of the Protein Fractionation Centre (PFC) in Scotland and the scope for establishing BPL/PFC partnerships;
- anticipated NHS demand for the next five years (and likely future trends);
- the decision to import plasma for the time being, and the commitment to return to UK plasma as soon as permitted to do so by the Government on the advice of the CSM;
- the need to ensure value for money in the use of UK fractionation capacity and a reasonable return on public investment;
- the relationship between NHS fractionated products and:

  - the blood products market;

  - the economic and professional activities of the wider blood transfusion services;

  and overall cost benefits to the NHS.

- intellectual property rights vested in the NHS fractionation centres and the role of fractionation centres as part of the wider NHS and the UK bio-medical industry.

In the light of all the above, to consult as appropriate and make recommendations to Ministers.

ANNEX B

The Rt Hon Stephen Byers Esq MP
Chief Secretary
Treasury Chambers
Parliament Street
London SW1P 3AG

6 November 1998

REVIEW OF UK BLOOD PRODUCTS MANUFACTURE

In my letter of 17 July to Alastair Darling I supported the need for a review of blood products manufacturing in the UK. We are now about to start that review which we have been developing with your officials and with Scottish Office colleagues.

I enclose the terms of reference for the review which have been agreed with Sam Galbraith and with your officials. The first stage of the review is to obtain detailed information from the Bio Products Laboratory (BPL) and the Protein Fractionation Centre (PFC) in Scotland. This is set out in the enclosed data requirements paper. We have asked for this information by early December with a view to producing an initial options paper for consideration in early January. As mentioned in my letter of 17 July, all possible options will be considered including closer integration with PFC and the range of Public Private Partnerships.

The aim is to reach final decisions on the best option by the end of this financial year. Your officials will be involved in all stages of this process.

I am copying this letter to Sam Galbraith, Mo Mowlam and Alun Michael.

FRANK DOBSON