CD-12.7

POLICY IN CONFIDENCE

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MANAGEMENT AND ORGANISATION OF THE NATIONAL BLOOD TRANSFUSION SERVICE (NBTS) AND THE CENTRAL BLOOD LABORATORIES AUTHORITY (CBLA)

Issue

1. Ministers are asked to consider proposals from the CBLA and the National Directorate of the NBTS

(i) to set up a "National Blood Authority" to improve the quality standards and efficiency and cost effectiveness within the NHS;

(ii) to 'decouple' the CBLA's manufacturing arm, the Bio Products Laboratory (BPL), to allow it to operate on a more commercial basis, and to pave the way for

(iii) a possible privatisation of BPL.

Recommendation

2. We can unreservedly recommend ministers to accept proposals (i) and (ii), which we believe would bring benefits to patients in terms both of more consistent quality and of lower price for blood and blood products. Proposal (iii) would also, we believe, be in the interest of the NHS. It would be politically sensitive, but we suggest that it could be presented in a positive way especially if combined with the proposal for a National Blood Authority.

Background

3. The existing management arrangements for the NBTS and the CBLA are described in the annex.

NBTS - PROPOSAL FOR A NEW NATIONAL BLOOD AUTHORITY

Issues

4. The NBTS is a national service in name only and the Regional Transfusion Centres (RTCs) within it are managed individually by the RHAs. A DH study in 1987 showed there were inefficiencies both within and between RTCs. These arose from the absence of a reliable management information system and the lack of cooperation and coordination between the RTCs and between them and the CBLA.

5. A National Directorate was set up in 1988 to address these concerns. Its role was a purely coordinating one and management responsibility for the RTCs remained with the regions. The Directorate has had some success in implementing a management information system and in coordinating some aspects of RTC work, in particular acting as a clearing house to put regions with temporary shortages of blood in touch with those in surplus. However, they consider they are nearing the limit of what can be achieved within the present voluntary structure.

6. The problems which remain and which point to the need for a stronger central role are

6.1 Quality standards. The quality of plasma varies considerably between regions, despite the Directorate's efforts. This is partly due to restrictions on capital funding for necessary capital investment (eg in quality control equipment). The removal of Crown Immunity from CBLA's products makes it all the more important that CBLA should be able to rely on consistent quality assurance in RTCs.

6.2 Cost effectiveness. There is already some duplication between regions of expensive facilities, and this is likely to get worse as new automated techniques for testing and processing of blood donations becomes available. There are also significant variations between regions both in the ease with which they can attract donors and in collection costs. A national overview of decisions on capital investment and on the amount of blood or plasma to be collected in each region would lead to significant savings.

NBTS Directive Proposals

7. Against this background and with the NHS reform tending to make it more difficult to coordinate the activities of the RTCs, the National Directorate commissioned a report from Ernst and Young into the role of a central body within the NBTS and the organisational options. A copy of that report is enclosed. The consultants concluded there was a need for a central body to address the problems of quality standards and cost effectiveness and they recommended a National Blood Authority as a contracting body rather than as a national manager of the RTCS. The main alternative option of a national management body to which RTCs would directly report was rejected as being more expensive without giving additional benefits.

8. Under the contracting model the NBA would obtain blood from the RTCs and contract for its supply to hospitals. The NBA would also contract with the BPL for the fractionation of plasma into blood products. The NBA would:

(i) lay down the quality specification for blood and plasma;

(ii) in matching supply and demand, favour the more cost effective producers; and

(iii) by directing capital would, over time, rationalise the RTC network.

9. We agree with the NBTS that the concept of a national contracting authority is the most appropriate way of tackling the problems described above. The contracting approach is consistent with the way that business is conducted in the reformed NHS. It would still allow genuinely local management issues - the recruitment of donors, organising collection sessions and the giving of advice and transfusion medicine to hospitals - to be managed at local level; while the contracting NBA would have sufficient leverage to achieve the required improvements in quality standards and the cost effectiveness. Finally informal soundings suggest that the proposals would be wlecomed, both by clinicians who use blood and blood prdoucts and by health authorities. We therefore recommend ministers to accept the proposal.

CBLA AND BPL - PROPOSALS FOR "DECOUPLING"

10. Last year the CBLA asked Touche Ross to examine the future strategy options for itself and the BPL, in the context of an increasingly competitive market for blood products and the likely appearance of synthetic substitutes for some products within 5 to 10 years. The consultants identified a conflict between the requirements that the BPL plant should operate as efficiently as possible and the need to observe certain sensitivities surrounding the use of the freely donated plasma. These sensitivities mean that BPL could not increase throughput by fractionating plasma in order to export products, nor could it undertake work for other suppliers using plasma from paid donors in view of the UK and EC aim of self-sufficiency based on freely donated plasma. It was also difficult for BPL to move into new production areas (eg synthetic products) because of the demands this would make on the NHS for R&D and other funding.

11. There emerged from the Touche Ross report the idea of resolving the conflict between the commercial and ethical aims by "decoupling" BPL from the CBLA and possibly privatising it. The BPL would act as sub-contractor to the CBLA for the fractionation of NHS plasma but would also be free to exploit new products and markets which would increase throughput and reduce costs. The CBLA would retain the ownership of the NHS plasma and the products made from it, and ensure their use for the benefit of NHS patients.

12. In their second report (copy attached) Touche Ross have considered this idea in more detail. The report was discussed with CBLA at their Annual Accountability Review meeting with PS(L) on 10 July.

Introducing the commissioner/provider discipline

13. As a first step, the CBLA wish to run a separate accounting system for BPL so that it becomes a separate cost centre within the organisation. This would make it easier to move to an independent BPL (private or NHS Trust) at some later date. However, the move can also justified in its own right as it would provide sharper accountability for the financial management of the plant; in effect, CBLA would be setting up an internal "management contract" with the BPL in much the same way as DHAs now do with their directly managed units. We recommend that ministers should give early agreement to this change to the internal accounting arrangements of the CBLA which should not in itself be contentious.

Introducing the commerical perspective

14. Going on from this, the consultants considered three options for a BPL "decoupled" from direct CBLA management:

- NHS Trust status;
- licensing commercial management to run it;
- outright sale, either a trade sale or management buy out.

15. The CBLA preference is for an outright sale. In each case the aim would be for the decoupled BPL to seek new business in the commerical market-place in order to make full use of the capacity at BPL's plant at Elstree, while contracting separately with CBLA to fractionate NHS plasma for NHS patients. They do not believe that either of the first options would bring the necessary freedoms to make full use of BPL's potential.They consider a management buy-out would not be viable but a joint management/trade buy out would be possible. They also think it would be possible for the Government to retain a strategic stake or 'golden share' in the venture but the constraints on the commercial partner should not be such as to impede full exploitation of the plant.

16. We agree that NHS Trust and licensing options would provide BPL with only a little more freedom. The Government would still own the plant and therefore it would be difficult to allow it to be used for example to fractionate paid plasma. The problem of funding new products would also remain.

17. The privatisation option would in our view allow the most efficient use of the plant. This would benefit the NHS in lower prices both for CBLA products and (through competition) for commercially supplied products. However, there are considerable political difficulties:

(i) there would be some criticism of the idea of a privatised BPL making profit from freely-donated plasma;

(ii) political apponents could portray the move as further evidecne of "selling off" the NHS;

(iii) setting the sale price would be difficult. It is highly unlikely that the £80m so far invested in BPL would be recovered.

18. It would therefore be tempting to postpone a decision. However, commercial companies may be more interested in purchasing BPL now than in a year or two. The EC move to promote community self-sufficiency in blood products made from freely donated plasma means that companies are looking around to get established in Europe. At present a few have expressed some interest in BPL but they may make decisions to invest elsewhere if there is no early prospect of privatisation.

19. On balance therefore we recommend that ministers should announce that they would be prepared to consider offers for commercial partners to buy an interest in BPL in order to open up new markets for products not involving UK plasma. The political difficulties would as far as possible be reduced by:

(i) coupling this with the announcement of proposals for a unified National Blood Authority, which is likely to be widely welcomed;

(ii) emphasising the important role of the NBA as custodian of plasma from volunteer UK donors and of products derived from it;

(iii) emphasising the expected benefits to NHS patients from more consistent quality and lower prices;

(iv) (possibly) retaining a "golden share", at least in the short term, as an extra safeguard.

Consultation and timing

20. If ministers agree in principle to the NBTS/CBLA proposa, a period of formal consultation would be advisable. Bodies to be consulted would include:

- RHAs
- the medical profession (JCC, Royal Colleges, BMA)
- other health care professions
- NBTS and CBLA staff associations.

Discussions with possible commercial partners could take place in parallel, leading to a final decision by ministers to go ahead in say October.

Decisions

21. The decisions about the NBA and the status of the BPL can be separated if Ministers wished to defer any decision on changing BPL status. However, the window of opportunity to privatise BPL, which we believe would be in the best interests of NHS patients, may not stay open for long.

22. Ministers are asked to decide:

i) if they wish to set up an NBA as a contractor for blood and plasma supplies, embracing the non-industrial role of the CBLA and the NBTS Directorate;

ii) if they are content for BPL to be set up as a separate accounting centre within the CBLA from 1 October 1991;

iii) if they wish subsequently to change the status of BPL and if so, to

- make it an NHS Trust
- license it to commercial management
- sell it or seek commercial partners in a jointly-owned company;
- if they agree that there should be a brief period of formal consulation on these proposals.

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ANNEX

NHS BLOOD SERVICES : MANAGEMENT AND FUNDING

1) The NHS blood services comprise the National Blood Transfusion Service (NBTS) and the Central Blood Laboratories Authority (CBLA).

NBTS

Management

2. Despite its name, the NBTS is actually 13 individually managed Regional Transfusion Centres (RTCs) (the south London Regions share a RTC). These RTCs collect blood and process it into various components; the cellular components are supplied to hospitals, the plasma recovered from blood (and some obtained from plasma donors) is supplied to the CBLA for fractionation into blood products such as Factor 8 and albumin.

3. A National Directorate was set up at the end of 1988 to coordinate the activities of the RTCs. This small body has no management authority over the RTCs, which remains with the RHAs.

Funding

4. From 1989, the RTCs recovered some of their operating costs for charging the CBLA for plasma, but otherwise they were funded by other RHAS. From 1 April 1991 the RHA funding has been replaced by income from handling charges levied on the hospitals what use the blood.

5. The total revenue cost of the NBTS is around £70m a year. Capital expenditure is not separately identified in the RHA accounts.

CBLA

Management

6. The CBLA is a Special Health Authority, set up in December 1982, mainly to manage the Bio-Products Laboratory (BPL). Up to 1978 the Lister Institute managed BPL on behalf of the Department and then we and NW Thames RHA jointly managed it until the CBLA was established. The BPL is a pharmaceutical plant which manufactures a range of blood products from the plasma supplied by the NBTS.

7. A new BPL plant was completed on the Elstree site in 1988. This was built with much greater capacity than its predecessor in pursuit of the policy of becoming self-sufficient in blood products using NBTS plasma. Self-sufficiency is now taken to mean that CBLA should be able to meet the demands for home produced products and should seek to maximise sales; clinicians are free to prescribe blood products from commercial suppliers if they prefer.

Funding

8. The CBLA sells the BPL products in competition with commercial products. It recovers most of its costs from sales income but it also has a DH cash limit to help with revenue costs and to fund capital products. In 1990/91 CBLA had sales receipts of £39 million and a DH cash limit of £12.6 million of which £5 million was for capital payments.