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POLICY IN CONFIDENCE

PS/PS(H)

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Date: 24 July 1992

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NATIONAL BLOOD AUTHORITY

1. This submission reports the recommendations of the DH/NHS Technical Working Group set up by Ministers to consider certain operational aspects of the proposed National Blood Authority (NBA). The submission also considers the case for going beyond the Working Group's recommendations and establishing the NBA as the managing Authority for the Regional Transfusion Centres (RTCs). We are seeking PS(H)'s agreement to the next steps required towards setting up the NBA as the managing Authority for the Blood Services.

Background

2. In September last year the Department consulted the NHS and appropriate professional medical bodies about the proposal to set up a National Blood Authority. The intention was for this new body to replace the National Directorate of the National Blood Transfusion Service (NBTS) as well as the Central Blood Laboratories Authority (CBLA). It was proposed that the new Authority would be the central contractor for blood; the NBA would contract with the RTCs for collection and processing and then supply it to hospitals under contract. In view of the general trend towards greater devolution in the NHS, it would have seemed anomalous to propose centralising the management of the RTCs in the NBA.

3. The consultation showed widespread support for the principle of an NBA but concerns were expressed about:

- a) its proposed role as the central contractor for blood - this was considered an unnecessarily complicated arrangement which would be less responsive to users demands than the present contract system between RTCs and hospitals;

- b) its proposed role in controlling capital for the RTCs - some Regional Transfusion Centres (RTCs) which had been well funded by their Regions were concerned they might lose out;
- c) the structure of the NBA - the RTCs saw the proposals as a takeover by the CBLA and feared that their interests would be subordinated to those of the Bio-Products Laboratory (BPL) and its fractionated blood products.

4. In light of the consultation Ministers confirmed their interest in establishing an influential NBA but deferred implementation until a Technical Working Group could resolve the operational issues.

Need for the NBA

5. The primary purpose in introducing a new National Blood Authority is to facilitate changes in the way that the blood services operate. The 13 regionally managed Transfusion Centres have variable standards of quality and efficiency; there is wasteful duplication and good practice is slow to spread round the network. These problems were recognised in a consultancy report in 1987 and resulted in a National Directorate being set up to co-ordinate RTC activities and promote efficiency. However the National Directorate has had only limited success as it has no "teeth" in its own right and has to rely on powers of persuasion. There is a need to set up a central Authority with sufficient power and the appropriate organisation to make the necessary changes to improve efficiency in the individual RTCs, to rationalise the network as a whole and ensure that consistent quality standards are achieved. There is an equally pressing need to ensure that the Regional transfusion network and Bio-Products Laboratory which fractionates plasma supplied by the RTCs work together for the benefit of the NBS as a whole. There have been tensions between these two sides of the blood service for many years. PS(H) is invited to re-confirm the establishment of the NBA.

Working Group Report

6. The report of the Technical Working Group is presented at the Annex. In summary the Group's main recommendations are that:

- a) the NBA should not be the central contractor for blood;
- b) it should be the strategic body for the blood services and pursue its objectives by promulgating quality standards and a common costing system. The NBA would not have line management responsibility for the RTCs but would control the supply of blood through its participation in the RTC business planning process with the right to approve or reject key features of RTCs business plans. The NBA would then monitor the RTCs

performance and be empowered to intervene should RTCs fail to meet their quality standards or production targets;

- c) the NBA should have control of capital investment in the RTCs so that it could develop the RTC network to meet the national requirements as cost efficiently as possible;
- d) the Group has recommended a balanced membership for the NBA which would give it the credibility it requires with all parts of the blood service.

7. The Working Group has also cautioned against granting NHS Trust status to RTCs before the NBA has developed its strategic plan for the future of the network. There could be difficulties if the NBA reached the view that a particular RTC should have a diminished (or no) role in the National network if the centre concerned was an independent trust.

NBA as Manager of the RTCs

8. For its deliberations the Working Group was asked to assume that the RTCs would continue to be managed by their RHAs and not by the NBA. The model which the Group has recommended would be an improvement on the present situation but the NBA would have to rely for its power on the backing of Ministers, the Management Executive and Regional General Managers rather than on statutory authority. Our legal advisers tell us there would be limited scope for the NBA to have powers over the RTCs while they remain managerially responsible to the Regions.

9. In discussion in the Working Group the possibility of direct management of the RTCs by the NBA was discussed and was not rejected outright by members from the RTCs. Under the Working Group's proposals there would be little scope for Regions to manage their RTCs in any meaningful way as the NBA would set operating standards and activity levels and Regions would provide RTCs with little more than pay and personnel services. On the other hand Regions might feel obliged to exercise wider control and come into conflict with the NBA. Moreover it is likely that the role as line manager for the RTCs will be incompatible with the future role of the Regions. For all these reasons we strongly favour direct management of the RTCs by the NBA. This will also give the NBA power itself to effect the necessary changes in the RTC network and make it more certain that the NBA will be able to realise the potential efficiency savings and quality improvements in the RTC network.

10. It will take a little time to devise a suitable structure for direct management of the RTCs and we would propose to set up a NH/NBA Planning and Implementation Group to carry through this work. However, in the meantime we think it is important that the NBA should be set up along the lines suggested by the Working Group

but with a firm commitment to direct management as soon as possible and no later than twelve months after the NBA is established. During its initial phase, clearly it would not be able to exercise fully all the functions envisaged in the Working Group's report. However, it could undertake valuable preparatory work in relation to such matters as determining the relative performance of RTCs, and the capital needs of the network which could then be acted on more quickly than if this work were postponed until a directly managed Authority had been set up.

11. If Minister is content with the proposed direct management role of the NBA, we shall discuss it with RBA Chairmen and Regional General Managers. We think they will be content but a few Regional Transfusion Directors may not welcome direct management.

BPL's role within NBA

12. Ministers decided last year that the Bio-Products Laboratory should be an integral part of the NBA. The Chairman of CBLA would still prefer it to have independent status outside the NBA.

13. The CBLA commissioned consultants in 1991 to advise on the future of the organisation. They concluded that the ethical and political constraints surrounding the use of the plasma derived from unpaid NHS donors made it difficult for BPL to operate as efficiently as their commercial rivals. In the consultants' view BPL needed the freedom to develop new product ranges using non-NHS plasma (possibly paid plasma) and to exploit potential new markets in Europe to utilise the capacity of their plant to the full.

14. The consultants suggested a range of options including privatisation and Trust status for the BPL. Ministers decided last July against any change in BPL's status partly because of concern that it would be seen as selling off part of the NHS, or as a preparatory step in that direction. BPL were instructed to take appropriate internal measures to improve cost efficiency and Ministers confirmed that BPL could both export products surplus to NHS requirements and undertake contract fractionisation for third parties provided the plasma came from voluntary unpaid donors.

15. The CBLA will use the opportunity of the Accountability Review on 15 October 1992 to press again for a change in BPL's status. A Trading Fund or NHS Trust would now be their preferred model.

Action by Office of Fair Trading (OFT)

16. A new factor to be considered is the OFT interest in BPL's activities. The removal of Crown Immunity from the NHS and development of the internal market has prompted OFT interest in areas where the internal market features of the reformed NHS and Government (and European) fair trading policies may be coming into conflict. The OFT has taken an interest in BPL over the past year

following complaints from its commercial rivals. It is concerned about BPL's exclusive use of NHS plasma, its subsidised price and its technical monopoly (ie in excess of 25% market share) for some products. The OFT is now considering whether it wishes to pursue these matters and will have further discussions with officials from DB and the Department of Trade and Industry.

Discussion of BPL's Status

17. Ministers will wish to hear the CBLA's views on the BPL status at the Accountability Review before making a final decision on its future inside or outside the NBA.

18. The BPL is at a disadvantage in competing with its commercial rivals because of the constraints of the public sector. Its access to capital to develop new products and update its facilities is restricted: sensitivities such as those surrounding the use of paid plasma make it more difficult for BPL to make full use of its capacity and thereby reduce costs to the NHS.

19. A more independent status even within the public sector, eg NHS Trust or Trading Fund, would ease some of the difficulties and put pressure on BPL management to improve the cost efficiency of its plant. This would also be in keeping with the Government's general policy that executive functions in the public sector should have more devolved, but accountable, managements. It will be vital for BPL to improve its cost efficiency if it is to compete effectively with the rivals already in the market and the increased competition from Europe likely to follow the introduction of the Single Market.

20. However, while independent status for BPL has attractions in the medium term, there are a number of reasons why it would not be appropriate in the immediate future:

- a) The BPL will need some time to get its finances in order, bring new products into production and resolve difficulties with its production line. BPL attribute the need for a subsidy largely to the plasma purchase price but there is also scope for improvement in its own efficiency.
- b) Market opportunities for BPL are most likely to present themselves in the EC. There is a commitment amongst the members to the concept of Community self-sufficiency in blood products made from voluntary unpaid donations. This might displace considerable amounts of commercial products made from paid donations. (eg Germany currently imports a large proportion of its needs.) Some countries might also be interested in contracting with BPL for fractionation of their blood and plasma. However it is very uncertain at this stage how the policy will develop and whether such opportunities will materialise.

- c) Whatever other opportunities present themselves, BPL will need a strong position in its home market and access to NBTS plasma if it is to remain viable. BPL is only now building a reputation as a reliable supplier and customer loyalty is helped by its association with the NBTS. If BPL came to be seen as just another supplier its sales to the home market could suffer. BPL needs some time to establish a firm reputation for the quality of its products and customer service.
- d) The way forward in the OFT investigation is uncertain. If BPL were privatised and their financial subsidy removed this could resolve the OFT's concerns but this would make BPL's selling prices uneconomic. Some form of independent status for BPL within the public sector, eg Trading Fund or NHS Trust is unlikely to remove OFT concerns. If BPL were to retain exclusive rights to NHS plasma and/or be given favourable contract terms for fractionisation for NHS needs, commercial rivals would persist with their allegations of unfairness.

21. In the circumstances it would be better for BPL to be an integral part of the NBA, at least for the next few years, while the new management establishes a strategic plan for the National blood services as a whole and addresses such issues as plasma pricing. BPL would nevertheless be managed through its Director who would be responsible to the NBA Board. It would be made a priority task for the BPL management to bring the organisation to financial viability. This would put it in the best position to develop more independently whether as a Trust, Trading Fund or some other status if outside circumstances so permitted. The separate accounting arrangements which now exist for BPL would be continued within the NBA to ensure clear management accountability for its performance. In summary, we think there would be no additional advantage at this time in moving BPL towards Agency status.

Other NBA Issues

Location

22. At present the CBIA (and BPL) are located at Elstree and the National Directorate of the NBTS is based in Manchester. It would be possible to bring them together in the NBA in one or other site. However, to do so is likely to be perceived as a takeover by one party or the other. It would be preferable for the NBA to be located on a neutral site; this would have the advantage that the NBA would be seen more obviously as a new body with a new purpose and not just a continuation of previous arrangements. Subject to PS(H)'s agreement, an option appraisal will be carried out and preparations made to find a suitable neutral location within reasonable distance of Elstree and close to the main motorway links.

Legal Aspects

23. It is intended that the NBA should be set up as a Special Health Authority with its key functions and powers set out in statutory instruments. These instruments would be subject to the negative resolution procedure and would need to be amended when the NBA assumed direct management responsibility for the RTCs.

NBA Funding

24. The NBA will bring together the existing CBLA (including BPL) and the National Directorate of the NBTS. However as the NBA will have additional functions there will be increased running costs of perhaps around £0.4M a year and setting up costs of around £0.1M. One of the main tasks of the NBA will be to promote greater efficiency in the RTC network and savings should be made over time to more than compensate for the extra costs. In a report to the NBTS Directorate, consultants indicated there could be scope for savings in the RTCs of several millions a year.

25. At present the CBLA is funded partly by sales income from BPL products and partly by cash limit from the Department; the NBTS Directorate is funded by cash limit. Initially this mixed arrangement would have to continue for the NBA but the aim would be to move towards recovery of NBA costs from the users of blood and blood products. However before moving to full cost recovery through prices the NBA would need to address issues concerning RTCs' and BPL's costs and BPL's competitive position in the blood product market. It seems likely therefore that the cash limit could only be phased out over time but a firm target would be set.

Timing

26. It is recommended that the target date for the NBA's formal establishment should be 1 April 1993. We would wish to get the Chairman and senior management in place as soon as possible so that essential preparatory work could be undertaken.

Decisions required

27. PS(H) is invited to confirm:

- a) that the National Blood Authority should be established (para 5)
- b) his agreement to setting up the NBA along the lines recommended by the Technical Working Group in the first instance but with a firm commitment to move to direct management of the RTCs as soon as possible and no later than twelve months after the NBA is formally established (paras 6-11)
- c) that BPL should be an integral part of the NBA (para 12-17)

- d) that subject to the results of a cost appraisal the NBA should be located at a neutral site (para 22)
- e) that the NBA should be set up as a Special Health Authority (para 23)
- f) that the target date for establishing the NBA as an operational unit should be 1 April 1993 (para 26)

Future Action

28. If PS(H) is content that the NBA should go ahead as described above officials will:

- a) discuss the proposals with NHS management;
- b) set up a planning and implementation group for the move to direct management;
- c) make soundings for a suitable Chairman and members;
- d) appoint senior managers from among those in CBLA/National Directorate and/or by open competition as appropriate;
- e) consider in detail with Solicitors the legislation required to establish the NBA;
- f) arrange for that an option appraisal to be undertaken and enter into negotiations for a suitable site for the NBA;
- g) consult the staff representatives of those who would be transferred to the new Authority (we are required to do this).

29. At some later stage PS(H) may need to answer an inspired PQ announcing these decisions.

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