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Performance Audit

Management of the Extension Option Review—Plasma Fractionation Agreement

Department of Health and Ageing

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
28 August 2003

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Department of Health and Ageing in accordance with the authority contained in the *Auditor-General Act 1997*. Pursuant to Senate Standing Order 166 relating to the presentation of documents when the Senate is not sitting, I present the report of this audit and the accompanying brochure. The report is titled *Management of the Extension Option Review–Plasma Fractionation Agreement.*

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely

P.J. Barrett
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

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Abbreviations/Glossary

AGS	Australian Government Solicitor
ANAO	Australian National Audit Office
ARCBS	Australian Red Cross Blood Service
Blood Review	Review of Australian Blood Banking and Plasma Product Sector
BODT	Blood and Organ Donation Taskforce
CPGs	Commonwealth Procurement Guidelines
CSL	CSL Limited
Finance	Department of Finance and Administration
FMA Act	*Financial Management and Accountability Act 1997*
FMA Regs	*Financial Management and Accountability Regulations 1997*
Health	Department of Health and Ageing
JCPAA	Joint Committee of Public Accounts and Audit
PFA	Plasma Fractionation Agreement
PM&C	Department of the Prime Minister and Cabinet
the Act	*Auditor-General Act 1997*
TGA	Therapeutic Goods Administration

Summary

Summary

Background

1. The States, Territories and the Commonwealth Governments spend around $350 million annually on the production and supply of blood and blood products for the Australian community. Commonwealth expenditure on plasma products under the Plasma Fractionation Agreement (PFA) between the Commonwealth Government and CSL Limited (CSL) represents more than one-third of the total annual expenditure on the sector by Australian Governments with expenditure under the PFA amounting to $124.1 million in 2001–02.

2. The material nature of this expenditure, together with the importance of plasma products to the care of Australian citizens with serious health problems, makes the ongoing procurement of plasma products an important public issue. Until 1 July 2003, the PFA was the largest single commercial contract managed by the Department of Health and Ageing (Health)[1]. When the contract was signed, in December 1993, it was estimated that total Commonwealth expenditure over the 10.5 years of the initial term of the PFA would be around $1 billion (in nominal terms). Actual expenditure by the Commonwealth under the contract over the first eight and a half years of the PFA (that is to 30 June 2002) totalled some $800 million.

3. Under the PFA, the Commonwealth was provided with an extension option that was a unilateral right to extend the agreement, under its existing terms and conditions 'to 30 June 2009, or such later date as the Commonwealth may decide', so long as it exercised the option and notified CSL of its decision to do so by 23 June 2002. Such a decision by the Commonwealth was in the sole discretion of the Commonwealth. Thus, CSL could not have refused to accept the extension had the Commonwealth chosen to exercise the option, nor could it have required the Commonwealth to exercise it. The PFA, had it been extended, would have become an enforceable contract upon notification to CSL of the Commonwealth's decision to exercise the option.

4. The PFA, and the plasma products supplied under it, is only one component of the wider Australian blood banking and plasma product sector. However, the context in which the PFA operates is important to any consideration of future arrangements for the supply of plasma products in Australia. In May 1999, the then Minister for Health and Aged Care announced the establishment

[1] On 1 July 2003, the new National Blood Authority (a Commonwealth statutory authority jointly funded by the State, Territory and Commonwealth Governments) took over responsibility for the management of the PFA.

of a review of the Australian blood banking and plasma product sector (the Blood Review). The review was to cover blood collection and banking activities as well as the processing and distribution of blood and blood products.

5. The Blood Review recommended fundamental reform of the blood sector both in terms of how it should be funded by the Commonwealth, State and Territory Governments and in terms of how it should be administered in future. Two of the Blood Review's terms of reference had particular reference to the Commonwealth's consideration as to whether or not to exercise its option to unilaterally extend the PFA after the Contract's expiry on 30 June 2004.

6. The then Minister's press release announcing the Blood Review indicated that it was expected to run for about a year. Accordingly, the Review Committee was originally expected to report to the Minister in mid 2000. However, in light of the scale and complexity of the task, the Committee's report was not finalised until March 2001. The Blood Review recommended that, rather than extending the current agreement, the Commonwealth should enter into a second shorter-term PFA with CSL at the expiry of the present Agreement to ensure that Australia's future needs for plasma products are met.[2]

Health's role

7. Until 1 July 2003, responsibility for the management of the PFA was located within the Blood and Organ Donation Taskforce (BODT) in the Acute Care Division of Health. The Department formed a high level *Steering Committee for the Future of Plasma Fractionation and Diagnostic Products Arrangements* in December 2001 that determined Health's advice to the Government on the PFA extension option. The BODT provided a secretariat to the Steering Committee.

8. During the Steering Committee's deliberations on the PFA extension option, the BODT advised the Committee that, in recommending the establishment of a new, shorter-term agreement between the Commonwealth and CSL, the Blood Review did not consider in detail the option to extend the PFA.[3] Health advised ANAO in response to the section 19 proposed audit report that:

> At no time did the Departmental Steering Committee accept the view in the paper, or take a decision to that effect. Therefore, this comment does not represent the view of the Departmental Steering Committee. The Department is of the opinion that the ANAO has taken this comment out of context, and that the ANAO's conclusion is not supported by the evidence.

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[2] *Review of the Australian Blood Banking and Plasma Product Sector*, March 2001, p. 89 and p. 91.

[3] Paragraphs 4.3 to 4.5 of the agenda paper prepared by the BODT for Item 2 of the Steering Committee's agenda for its 18 April 2002 meeting.

9. ANAO notes that no reference is made in the minutes of the 18 April 2002 Steering Committee meeting that the Committee did not accept the BODT's view that the Blood Review did not consider in detail the option to extend the PFA.[4]

10. In total, the Steering Committee met four times between 14 December 2001 and 18 April 2002 before reaching a decision on its recommendation regarding the extension option contained in the PFA. At the fourth Steering Committee meeting on 18 April 2002, two months before the option expired, the Committee reached the decision that it should recommend to the Government that the option to extend the PFA not be exercised, given that the Committee had concluded that the disadvantages of extending the current PFA outweighed the advantages.[5] The Steering Committee's recommendation and other advice on this matter were forwarded to the Minister for Health and Ageing on 11 June 2002 and 20 June 2002. The Minister accepted the Department's recommendation and chose not to exercise the option on 21 June 2002.

Audit scope

11. The Joint Committee of Public Accounts and Audit (JCPAA) of the Parliament conducted an inquiry into Audit Report No.24 1999–2000, *Commonwealth Management and Regulation of Plasma Fractionation*. The audit report, tabled in December 1999, examined Health's management of the PFA and regulation of plasma fractionation. In light of the JCPAA's findings in relation to its inquiry into the audit report, the Committee's Report No.378 included a recommendation that ANAO undertake a timely performance audit of Health's handling of the PFA extension review.

12. ANAO's response to the JCPAA recommendation was to include a proposed audit of the PFA extension review in its 2001–02 Audit Work Program. The audit commenced in late June 2002 following the expiry, on 23 June 2002, of the Commonwealth's unilateral option to extend the PFA. The scope of the audit was limited to the planning and conduct of the PFA extension option review. The objective of the audit was to review the efficiency and effectiveness of

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[4] The BODT's advice was included in Agenda Paper 2 prepared by the BODT for the Steering Committee's fourth meeting on 18 April 2002 and this paper recommended that the PFA extension option not be exercised. The ANAO notes that the BODT prepared the material in question in response to a direction of the Steering Committee contained in the minutes of its third meeting, on 15 March 2002. The Steering Committee's minutes for the 15 March 2003 meeting contained the following direction that: '…..a paper be prepared exploring the question of whether or not to extend the current [PFA] beyond 30 June 2004. The paper is to (i) examine the material prepared for the Review of the Australian Blood Banking and Plasma Products Sector (the Blood Review) and report on the extent to which the above question was addressed and the adequacy of the evidence on which it was based;……'

[5] Record of Decision of the *Steering Committee for the Future of Plasma Fractionation and Diagnostic Products Arrangements*, 1 May 2002.

Health's planning and conduct of this review, in accordance with the JCPAA's recommendation.

13. In June 2002, Health proposed to ANAO that the audit scope should also include the Department's subsequent work on securing a supply of plasma and related products beyond 30 June 2004. Health advised ANAO that the Department's reasoning was that the full implications of the planning and conduct of the extension review cannot be properly assessed until this subsequent work is completed in 2004.

14. ANAO noted that, as Health did not expect the process for securing plasma and related products beyond the expiry of the PFA to be completed until mid-2004, any audit of the complete process would not be able to be completed until early 2005. Accordingly, rather than delay reporting to the Parliament, and in accordance with the JCPAA's request for a timely audit of the PFA extension review, ANAO proceeded with the requested limited scope audit. The audit builds upon previous performance audits undertaken in this area by ANAO.[6]

15. Health's views and opinions on a number of matters raised in this audit report differ from those of the ANAO. ANAO sought to resolve these issues by issuing four issues papers to Health in December 2002. Following Health's response to these papers in March 2003, ANAO issued a consolidated discussion paper to the Department later that month and a further discussion paper was issued in May 2003.

16. Health's April 2003 comments on the first discussion paper required ANAO to take legal advice on issues raised by Health relating to section 37 of the *Auditor-General Act 1997* (the Act).

17. Subsection 37(1) of the Act provides that the Auditor-General must not include particular information in a public report if the Auditor-General is of the opinion that disclosure would be contrary to the public interest for any of the reasons set out in subsection 37(2) of the Act. In May 2003, ANAO issued a further discussion paper to Health, which had been revised in light of the Department's comments and ANAO's legal advice. This paper was also provided to the Departments of Finance and Administration (Finance) and the Prime Minister and Cabinet (PM&C).

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[6] In addition to Audit Report No.24 1999–2000, *Management and Regulation of Plasma Fractionation*, ANAO undertook an earlier audit, Audit Report No.14 1995–96, *Sale of CSL, Commonwealth Blood Product Funding and Regulation*.

Key findings

Timeliness of the process

18. Audit Report No.24 1999–2000, tabled in December 1999, noted the importance of the Commonwealth being well prepared for taking a decision on the PFA extension option. The report recommended that Health commence early planning for the expiry of the initial term of the PFA contract to ensure that the Commonwealth could advise CSL of its preferred position by the required date.

19. In the event, the Steering Committee process for determining Health's recommendation to the Government on the PFA extension option commenced in December 2001, some six months before the expiry of the option. ANAO found that, on Friday 21 June 2002, the last working day before the expiry of the option on 23 June 2002, the Minister accepted Health's recommendation not to exercise the PFA extension option. On the same day, the Department notified CSL in writing of the Commonwealth's decision.

Value for money

20. ANAO would have expected that some substantive risk analysis, including the availability and costs of alternative options for the future provision of plasma products after the expiry of the PFA, would have been explored by Health in advance of making a decision on the PFA extension option. This would be necessary in order to make an informed judgement about the value of exercising the option. However, this did not occur.

21. In this regard, ANAO notes that, when Health briefed Finance in June 2002 on the recommendation not to exercise the option, Finance indicated concern about the breadth of the risk analysis undertaken by Health, particularly in relation to costs. Finance advised that it would want to see an economic analysis of the savings that Health envisaged would be made under a new PFA before supporting the advice not to exercise the extension option, despite the difficulties of the current PFA.

22. The advice provided to Health's Steering Committee regarding the relative value for money of the PFA extension option was formulated on the basis of limited analysis of the current contract and preliminary testing of the operation of the contract in response to the likely effects of a number of possible changes to the product mix over the term of the possible PFA extension. The Committee concluded that it had sufficient information before it, through the processes it had undertaken, to make the decision in regard to the PFA extension option. However, in the ANAO's view, Health's Steering Committee would have benefited from more substantive information on the costs and benefits of the option.

23. Under the PFA, payments to CSL are based on a fixed price for each unit of product. However, there are two prices set for each product. The higher price is paid by the Commonwealth on a threshold level for each product that is broadly in line with CSL's production levels at the time the PFA was signed in late 1993. The second tier price, which is significantly lower than the first tier price, is paid on all production above the threshold level and aims to recover variable costs.[7] By 2001–02, nearly 25 per cent of the total payments under the PFA were for products at the lower tier-two price, representing a more than four-fold increase as compared to 1995–96 expenditure.

24. The Steering Committee received legal advice on 18 April 2002, which it relied on in deciding to recommend that the PFA extension option not be exercised. A key part of the legal advice was the proposition that, even if the Commonwealth were to source a significantly greater proportion of its requirements outside of the PFA, the revenue received by CSL must be no less than the revenue received for the previous financial year, as indexed under the contract (that is, CSL's revenue would not decline even if it manufactured less product under the PFA). The record of the Steering Committee's decision identified this as one of the three main disadvantages of the current PFA.

25. ANAO received legal advice that it is not clear that Health's interpretation of the PFA's terms, such that CSL's revenue is not able to fall from that of the previous year, is a correct interpretation of the operation of the PFA.[8] Subsequently, Health obtained advice from the Chief General Counsel at the Australian Government Solicitor (AGS) that conflicted with the earlier advice obtained by ANAO. Consequently, ANAO can only note the differences in legal opinions. However, the legal advice obtained by Health from AGS did conclude that Health's own legal adviser's general statement as to guaranteed revenue overstated the position as to guaranteed revenue because it did not spell out that, in AGS' view, this only happens 'when a certain series of events occurs.'

26. CSL's revenue under the PFA has risen in each year of the contract to date. ANAO notes that there have already been occasions when Health has

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[7] See CSL Limited Prospectus, April 1994 p. 84 and *Review of the Australian Blood Banking and Plasma Product Sector*, March 2001, p. 88.

[8] ANAO's legal advice was that:

Paragraph 11 of Schedule B (paragraph B11), which *prima facie* has the effect of providing continuity of revenue for CSL Ltd in the PFA in the absence of agreement by the parties to the contrary, is inconsistent with a principal clause of the contract, clause 3.2.6. It is our view that paragraph B11 and the clause probably cannot be construed in a manner to make them consistent, because they require opposite results.

Where there is a conflict between a clause and a term in a Schedule, then the clause prevails (clause 1.2.9).

Subject to a qualification concerning the intention of the parties, which may have to be explored further, we do not think that the inconsistency can be remedied by omitting a word or words from the PFA. As a result, clause 22.2 would have the effect of severing paragraph B11 from the PFA.

notified CSL that it required less than the specified minimum volume of a particular product for a year. ANAO understands that CSL has yet to seek to use the provisions of the PFA to seek an adjustment to the price of such a product.

27. ANAO found a lack of detailed work undertaken during the Steering Committee process to clarify the contract's terms including analysis of potential for benefits to the Commonwealth from continuation of the existing terms of the two-tier pricing system for plasma products that applies under the PFA.

Consultation

28. At no time, prior to recommending to its Minister that the PFA extension option not be exercised, did Health consult with CSL about the PFA extension option. ANAO notes that, when major contracts incorporate an option to extend the contract, it would be unusual for the parties not to consult in attempting to inform themselves about the pros and cons of exercising that option, prior to its expiry.

29. The ANAO considers that effective communication between the parties is a prerequisite to good contract management both for ongoing operations and for strategic purposes. The absence of dialogue in relation to the strategic management of an important Commonwealth contract is, in ANAO's experience, also unusual, particularly given Health's advice to ANAO that the cost involved for the supply of plasma products in the five years following the expiry of the PFA could be some hundreds of millions of dollars.

Advice to Government

30. Following consultations with PM&C, Health provided a brief to the Minister for Health and Ageing on 11 June 2002, advising that the Steering Committee recommended that the PFA extension option should not be exercised and that the Minister write to the Prime Minister recommending that he agree to the Government not exercising the option.

31. Health met with officers from PM&C on 12 June 2002. At the meeting, Health provided a briefing on the background to the recommendation not to extend the PFA. The Department also provided the reasons it considered that the risks it would not succeed in negotiating a new agreement were of an acceptable level. Following the meeting, the PM&C officers indicated that they would be talking to Finance before completing a briefing for the Prime Minister on the Minister for Health and Ageing's letter and suggested Health should also contact Finance ahead of this to provide the necessary background and information. Health subsequently arranged a meeting with officers from Finance and Treasury on 14 June 2002.

32. At the meeting on 14 June 2002, amongst other matters, officers from Finance questioned the timeframe available for the decision on the option, noting that there was little time available for detailed consultation with departments and their Ministers. The Finance officers also indicated concern about the breadth of the risk analysis undertaken by Health, particularly in relation to costs.

33. In the week that the PFA option expired, Health responded to Finance's questions indicating that estimates of the financial impacts of all elements of the proposed new arrangements, including the assumptions underpinning them could not be provided because Health was not proposing new arrangements at this point. Health advised it was just providing advice to Government on whether or not the Commonwealth should exercise the option to extend the current agreement.

34. The Minister for Health and Ageing wrote to the Prime Minister on 16 June 2002 seeking his agreement to the Government not exercising the PFA extension option. Following oral advice from PM&C, on 20 June 2002, that the Minister for Health and Ageing had full authority to make the decision in relation to the PFA extension option, Health provided another brief to its Minister late on that day advising her of this and requesting her to make the decision. On 21 June 2002, the Minister accepted the Department's recommendation that the PFA extension option not be exercised.

Procedural ambiguity

35. Health advised ANAO, in February 2003, that its internal legal advice was that Regulations 8 to 13 of the *Financial Management and Accountability Regulations 1997* (FMA Regulations), dealing with the specific decision making requirements for approving and entering into commitments to spend public money, did not apply to the decision not to extend the PFA. ANAO has again received conflicting legal advice on this issue. ANAO considers that the opportunity to exercise an option in a contract creates economic benefits and costs. Clearly, if in exercising, or not exercising, the option the spending of more public money is involved, then the Commonwealth financial management framework applies. ANAO considers that it is undesirable that there be ambiguity around the procedures to be applied by Commonwealth agencies when deciding whether or not such an option should be exercised.

36. Health's February 2003 internal legal advice also stated 'the [Commonwealth Procurement Guidelines (CPGs)] do not contain any requirements or principles which apply specifically to a decision on whether or not to exercise an option under a contract.' ANAO agrees that the CPGs do not currently specifically contain any guidance for agencies on options nor do they

provide any specific advice as to whether the CPGs apply in circumstances where agencies decide not to exercise an option. ANAO considers that there would be merit in Finance, as the responsible agency, reviewing the CPGs to determine how to specifically address this issue.

Overall conclusion

37. The request of the JCPAA was for a timely performance audit of Health's handling of the PFA extension review. This was the focus of the audit. ANAO considers that insufficient information was available to Health's Steering Committee to allow it to form an objective view on the financial merit of the advice it provided to the Minister on the value of the PFA extension option. ANAO makes no judgement about whether or not the decision not to extend the current agreement was a correct decision.

38. Health advised ANAO, in July 2003, that the Department did not agree with this conclusion and stated:

> The Department notes that, in ANAO's opinion, the Steering Committee had insufficient information to form an objective view of the value of the extension option. The Department disagrees with this finding. The finding is based on the ANAO's conclusions about the legal advice on the revenue maintenance provisions of the PFA and the fact that the Steering Committee did not formally assess the future costs and benefits of the two-tier pricing arrangements that would have persisted had the contract been extended.
>
> In relation to the first point, and in response to the audit, the Department obtained advice from the Chief General Counsel at the Australian Government Solicitor (AGS) that substantially confirmed the advice received by the Steering Committee. The Department considers that it had been prudent in seeking the legal advice, and also considers that the AGS advice supports the basis for the Steering Committee's consideration of the value for money issues.
>
> In relation to the second point, the Department considers that the basis for the ANAO's conclusion relates to a perception that the Department did not fully appreciate the future financial value of the two-tier pricing arrangement. The Department's view is that the most important analysis required in relation to the two-tier pricing arrangements was whether the benefits would continue if the extension option were taken up. Having undertaken this analysis, the Department concluded that, based on its assessment of future product requirements, the arrangements might be of limited financial value.
>
> The Steering Committee identified that a major challenge for the future was to deal with the increasing demand for substitutes for some plasma products and with potential over-supply of some products. In particular, there was a likelihood that beyond June 2004, synthetic products would increasingly replace plasma-derived coagulation products. Under the two-tier pricing arrangements, any fall in demand

increases average prices and if demand fell below the minimum volume, the current PFA provides for the possibility of a compensating price adjustment.

The Steering Committee concluded that the benefits of the two-tier pricing arrangements would be more than offset by these two countervailing factors. This was the crucial analysis required at the time.

39. ANAO notes that, in the Steering Committee's 1 May 2002 record of its decision on the option, there is no explicit consideration of the value of the two-tier pricing regime. As discussed in para 23 above, by 2001–02, the proportion of total payments under the PFA for products at the lower tier-two price had increased by more than four-fold as compared to 1995–96 expenditure. The Steering Committee concluded that the current pricing arrangements were unlikely to be the most advantageous available to the Commonwealth (see para 3.19). The main analysis underpinning this conclusion appears to have been a scenario analysis undertaken on 16 April 2002 by the Steering Committee's advisers together with the BODT. This scenario analysis did not include any data on the costs of alternative options. As mentioned in para 32, at a meeting with Health on 14 June 2002, Finance officers indicated concern about the breadth of the risk analysis undertaken by Health, particularly in relation to costs (also see paras 4.42 to 4.45).

40. Notwithstanding Health's comments outlined above, ANAO concludes that there were five key areas where improvements could have been made in Health's handling of the PFA extension option review as follows:

- Despite early warning by ANAO in December 1999, and coverage of this issue by the JCPAA during 2000, the Steering Committee process for this complex issue was not commenced until December 2001, some six months before the expiry of the extension option.
- There was a lack of appreciation by the Department of the nature of the analysis required to underpin adequate advice to the Government on whether or not to exercise the option.
- The Steering Committee determined that it did not have to establish the best value for money approach for the future supply of plasma products before making its recommendation as to whether or not to exercise the extension option.
- In reaching its conclusions about extending the PFA, at no time did the Department consult with CSL.
- The process to advise the Government on Health's recommendation not to exercise the option was undertaken very late, restricting the opportunity for adequate consultation with senior Ministers and detailed consideration of the Department's advice.

Agency responses

41. Health's full response to the section 19 proposed audit report can be found at Appendix 1. Health advised ANAO that the following was its summary response:

> The Department's response is framed in the context of the overall policy and procurement environment in which the PFA extension decision was taken. In summary, the Department considers that it:
>
> - adopted a timely and effective approach to the PFA extension review, including consideration of value for money issues;
> - fully appreciated the nature of the analysis required to underpin advice to Government;
> - provided advice to the Minister based on sound analyses of the information available, in particular the findings of the comprehensive National Blood Review; and
> - met its obligations under the PFA in terms of timing of the decision and advice to CSL.
>
> The audit was conducted at a point that meant that it reflected only a part of the whole policy and procurement process relating to future arrangements for the supply of plasma products. There are still policy matters relating to the future arrangements that are to be decided.
>
> The Departments views and opinion on a number of matters raised in the report differ from those of the ANAO.

42. PM&C provided correspondence, jointly signed by Health, advising of further information identified in the Departments, since the issuing of the section 19 proposed report in June 2003. On the basis of this information, the Departments requested some amendments to the section of the report that discusses interaction between the two agencies on 7 June 2002 (see para 4.38). PM&C also advised ANAO that the Department did not have any further comments on the conclusions reached in the audit.

43. Finance advised ANAO that it was 'satisfied that the proposed report accurately reflects the nature, content and extent of the interaction between Finance and other agencies including Health, PM&C and the ANAO on this issue.'

44. The focus of the audit, in accordance with the JCPAA recommendation, was Health's planning and conduct of the PFA extension option review. In this circumstance, the audit was chiefly concerned with specific past events. However, during the course of the audit, Health brought to ANAO's attention its view that the FMA Regulations and the CPGs do not apply to a decision not to exercise

a contractual option. ANAO and Finance, the agency with policy responsibility for the FMA legislation and the CPGs, do not agree with Health's view.

45. However, given that there may be uncertainty about this issue, ANAO made one recommendation in the audit report suggesting that Finance enhance the guidance provided in the CPGs by including specific advice to agencies on the procedures to be applied to evaluating options in materially important procurement contracts. Finance agreed with the recommendation and has advised ANAO that it will investigate the inclusion of the consideration of options within the whole-of-life assessment of value for money when next updating the CPGs. In the interim, Finance will consider distributing guidance in a Commonwealth Procurement Circular on the consideration of options in materially significant contracts.

Recommendations

Set out below is ANAO's sole recommendation, with the relevant report paragraph reference, and Finance's abbreviated response. Finance's full response appears following the recommendation in the body of the report.

Recommendation No.1 Para 4.62

ANAO *recommends* that the Department of Finance and Administration enhance the guidance provided in the Commonwealth Procurement Guidelines by including specific advice to agencies on the procedures to be applied to evaluating options in materially important procurement contracts.

Finance Response: Agreed.

Audit Findings and Conclusions

1. Introduction

This chapter outlines the background to the audit; describes the audit approach; and confidentiality of information issues addressed in the course of the audit.

Background

1.1 Products derived from human plasma are critical healthcare products and for some of these products there is increasing demand. Plasma is the liquid portion of blood that contains various proteins. Currently, plasma products include immunoglobulins (used, among other things, to help patients fight severe infections); albumin (a plasma volume expander used in emergency trauma situations including shock, surgery and burns); and haemostatic factors (used to treat people such as sufferers of haemophilia who lack sufficient clotting factors in their blood). Until recent years, demand for plasma products was driven primarily by the need for haemostatic factors but now the products in shortest supply are immunoglobulins.

1.2 Given the importance of plasma products in the health system, successive Commonwealth Governments have ensured that Australia has remained largely self-sufficient in the production of these products. Indeed, Australia is a signatory to a 1975 World Health Assembly resolution that advocates self-sufficiency and voluntary non-remunerated donations as the optimal system for ensuring the safety, quality and supply of a nation's plasma products.[9]

1.3 The PFA between the Commonwealth and CSL provides for the processing of plasma products by CSL from Australian-sourced plasma, which is collected by the Australian Red Cross Blood Service (ARCBS) from volunteer donors. Until 1 July 2003, the blood collection costs of the ARCBS were shared between the Commonwealth and State and Territory Governments with the Commonwealth meeting some 40 per cent of the cost and the State and Territory Governments meeting 60 per cent. In addition, until 1 July 2003, the Commonwealth funded 100 per cent of the costs of processed plasma products supplied by CSL under the PFA[10]. These products are provided free of charge to the Australian community.

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[9] Resolution WHA 28.72 of the Twenty-eighth World Health Assembly, 29 May 1975–*Utilisation and Supply of Human Blood and Blood Products.* The resolution urged Member States:

(1) to promote the development of national blood services based on voluntary non-remunerated donation of blood; and

(2) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products.

[10] On 1 July 2003, the National Blood Authority (a Commonwealth statutory authority jointly funded by State, Territory and Commonwealth Governments) commenced operations and took over management of the PFA.

1.4 The State, Territory and Commonwealth Governments spend around $350 million annually on the production and supply of blood and blood products for the Australian community. Commonwealth expenditure on plasma products under the PFA represents more than one third of the total annual expenditure on the sector by Australian governments, with expenditure under the PFA amounting to $124.1 million in 2001–02. The material nature of this expenditure, together with the importance of plasma products to the care of Australian citizens with serious health problems, makes the ongoing procurement of plasma products an important public interest issue.

1.5 The initial term of the December 1993 PFA expires on 30 June 2004. Under the terms of the Agreement, the Commonwealth was provided with an extension option that was a unilateral right to extend the PFA, under its existing terms and conditions 'to 30 June 2009, or such later date as the Commonwealth may decide', so long as it exercised the option and notified CSL of its decision to do so by 23 June 2002.[11] Such a decision by the Commonwealth was at the sole discretion of the Commonwealth. Thus, CSL could not have refused to accept the extension had the Commonwealth chosen to exercise the option, nor could it have required the Commonwealth to exercise it. The PFA, had it been extended, would have become an enforceable contract upon notification to CSL of the Commonwealth's decision to exercise the option. The Minister for Health and Ageing decided on 21 June 2002 not to exercise this option and the Department so advised CSL on the same day. The main events associated with the PFA since December 1993 are outlined in Figure 1.1 below.

[11] Clauses 2.3.1 to 2.3.5 of the PFA.

Figure 1.1

Plasma Fractionation Agreement Key Events

December	23	1993	PFA signed by CSL and the Commonwealth.
May		1994	CSL Ltd sold by way of 100 per cent public float of shares.
November	29	1995	ANAO Audit Report No.14 1995–96 *The Sale of CSL—Commonwealth Blood Product Funding and Regulation* is tabled.
April		1996	Completion of the Initial Plasma Fractionation Agreement Review.
February		1997	Joint Committee of Public Accounts Report 349 *Review of Auditor-General's Reports 1995–96.*
May	10	1999	Then Minister announces the commencement of the Review of Australian Blood Banking and Plasma Product Sector (Blood Review).
December	22	1999	ANAO Audit Report No.24 1999–2000 *Commonwealth Management and Regulation of Plasma Fractionation* is tabled.
October		2000	Joint Committee of Public Accounts and Audit Report 378 *Review of Auditor-General's Reports 1999–2000 Second Quarter.*
March	27	2001	Blood Review report submitted to the then Minister.
June	8	2001	Then Minister issued Blood Review Report publicly and undertook to consult with the States and Territories and other stakeholders on a detailed implementation plan for the Review's proposals.
September	28	2001	Then Minister announced that the Australian Health Ministers had agreed to implement the Blood Review's key recommendation to establish a National Blood Authority.
October		2001	Planning for the Departmental Steering Committee process commences.
December	14	2001	First Steering Committee Meeting—Terms of Reference agreed.
April	18	2002	Steering Committee reaches decision to recommend to Government not to exercise the PFA extension option.
May		2002	Health commences consulting with PM&C on the appropriate means for putting the Steering Committee's recommendation to Government.
June	11	2002	Health provides Minute to the Minister providing her with a strategy for her to recommend to the Prime Minister that the Government not exercise its option.
	16	2002	Minister for Health signs letter to the Prime Minister seeking his agreement to the Government adopting a decision not to exercise the extension option.
	20	2002	The Chair of the Steering Committee is advised that verbal advice has been obtained from a senior officer in PM&C that the Minister had full authority to make the decision in relation to the PFA extension option.
	20	2002	The Department sends a minute to the Minister recommending she make the decision not to exercise the extension option.
	21	2002	Minister makes the decision not to exercise the extension option.
	21	2002	Health sends a facsimile to CSL advising of the Commonwealth's decision not to exercise the extension option.
	23	2002	PFA extension option expires.
June	30	2004	Expiry of the PFA.

Source: ANAO analysis of Department of Health and Ageing records.

Plasma Fractionation Agreement

1.6 The major manufacturing process involved in the production of plasma-derived products is fractionation. Fractionation is a separation process by which the large-scale separation of plasma into its various protein components (or fractions) is achieved. In May 1994, the Commonwealth sold by way of a public float all of its shares in CSL, the sole manufacturer of such products in Australia. Gross proceeds of the sale of CSL were some $299 million. To ensure that Australia's self-sufficiency in plasma products was protected following the privatisation of CSL, in December 1993 the Commonwealth entered into a long-term contract with CSL for the supply of these products - the PFA.[12] The initial term of the PFA was 10.5 years, from 1 January 1994 until 30 June 2004.

1.7 Until 1 July 2003, the PFA was the largest single commercial contract managed by Health and responsibility for its management was located within the BODT in the Acute Care Division of the Department.[13] When the Contract was signed, in December 1993, it was estimated that total Commonwealth expenditure over the 10.5 years of the initial term of the PFA would be around $1 billion (in nominal terms). Actual expenditure by the Commonwealth under the Contract over the first eight and a half years of the PFA to 30 June 2002 totalled some $800 million.[14]

1.8 CSL's plasma fractionation facility at Broadmeadows in Victoria is the only plasma fractionation plant currently operating in Australia. Due to the national interest in ensuring continuity of supply of the critical healthcare products manufactured by CSL, the *Commonwealth Serum Laboratories Act 1961*, as amended by the *CSL Sale Act 1993*, provides a statutory mechanism to enforce the specific performance of the PFA if CSL fails, without just cause or excuse to manufacture product or otherwise breaches the contract.[15] The Act also includes provisions preventing CSL from encumbering the Broadmeadows facility without Commonwealth consent and restricts CSL's ability to dispose of plant and equipment at the facility without such consent.

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[12] Similarly, at the same time the Commonwealth also signed another contract with CSL, the Diagnostic Products Agreement (DPA) to provide for continued supply of a range of diagnostic products for blood testing, typing and cross-matching produced by CSL The DPA had a shorter term than the PFA, seven and a half years as compared to the ten and a half year term of the PFA. The contract has been extended three times since the original term expired on 30 June 2001 and is now due to expire on 30 June 2004, the same expiry date as the PFA. On 18 June 2002, the Minister for Health and Ageing announced the extension of the DPA to 30 June 2004 but noted that, prior to that date, the Department would be undertaking market-testing to identify whether there are viable competitors for CSL in this area.

[13] On 1 July 2003, the new National Blood Authority (a Commonwealth statutory authority jointly funded by the State, Territory and Commonwealth Governments) took over responsibility for the management of the PFA.

[14] ANAO analysis of information provided by Health.

[15] Division 4–Injunctions to ensure performance of plasma product contracts; Part 3A–National Interest restrictions on CSL Limited; *Commonwealth Serum Laboratories Act 1961*.

Audit approach

1.9 In light of the material nature of the PFA contract, and the critical importance to the Australian community of plasma-derived products, it has previously been the subject of an ANAO performance audit. Audit Report No.24 1999–2000, *Commonwealth Management and Regulation of Plasma Fractionation*, examined Health's management of the PFA and regulation of plasma fractionation. The audit report was tabled in December 1999. It was the first occasion on which ANAO had reviewed the management of a material long-term contract let in association with a significant asset sale.

1.10 The audit report noted the importance of the Commonwealth being well prepared to take a decision on the PFA extension option and recommended that Health: commence early planning for the expiry of the initial term of the PFA contract to ensure that the Commonwealth could advise CSL of its preferred position by the required date; and ensure that, in considering options for future supply of plasma products following the expiry of the initial term of the PFA, the Department sought appropriate expert legal, financial and product advice before entering into any contract negotiations.[16] Health accepted this recommendation.

1.11 The JCPAA conducted an inquiry into Audit Report No.24 1999–2000. In light of the Committee's findings from its inquiry into the audit report, Recommendation No.10 of JCPAA Report No.378 of October 2000 was as follows:

> The Committee recommends that the Australian National Audit Office undertake a timely performance audit of the Department of Health and Aged Care's handling of the Plasma Fractionation Agreement extension review.[17]

1.12 ANAO's response to the JCPAA recommendation was to include a proposed performance audit of the PFA extension review in its 2001–02 Audit Work Program. The audit commenced in late June 2002 following the expiry, on 23 June 2002, of the Commonwealth's unilateral option to extend the PFA.

1.13 The scope of the audit was limited to the planning and conduct of the PFA extension option review. The objective of the audit was to review the efficiency and effectiveness of Health's planning and conduct of this review, as recommended by JCPAA.

1.14 The PFA extension option expired on 23 June 2002. ANAO conducted an opening interview with Health on 25 June 2002. At this meeting, Health proposed to ANAO that the audit scope should also include the Department's subsequent

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[16] See Recommendation No.2, Audit Report No.24 *Commonwealth Management and Regulation of Plasma Fractionation*.

[17] JCPAA Report No.378 October 2000, *Review of Auditor-General's Reports 1999–2000, Second Quarter* p. 41.

work on securing a supply of plasma and related products beyond 30 June 2004. Health advised ANAO that the Department's reasoning was that the full implications of the planning and conduct of the extension review could not be properly assessed until this subsequent work is completed in 2004. Health's detailed views, as provided in the Department's response to the June section 19 proposed audit report, are as outlined in Figure 1.2.

Figure 1.2

Health's comments on the timing and scope of the audit

The ANAO notes at paragraph 1.11 of the report that in October 2000 the JCPAA recommended that the ANAO undertake a timely performance audit of the Department's handling of the PFA extension review.

The ANAO commenced the audit in June 2002, immediately after the extension deadline had passed. At that time, the Department advised the ANAO (at the entry interview for this audit) that the overall policy and procurement review process for plasma products was still continuing, and that the PFA extension decision was only one step in the overall policy and procurement process which would go through until the point when a new contract was signed for plasma products.

The Department suggested that an audit of the complete process of setting in place new plasma fractionation arrangements beyond 30 June 2004 might be more appropriate, because it would enable the Department's conduct of the extension review element to be considered as part of the broader procurement process and assessed in terms of the outcome of that process.

In February 2003, the Secretary of the Department wrote to the Auditor-General expressing concerns about the timing of the audit, noting that the Department was mid-way through the process, and that there remained policy matters that were yet to be decided.

In this context, the Department noted its view that a 'timely' audit as requested by the JCPAA should mean 'well timed or appropriately timed and not simply rapid'. The Secretary of the Department invited the ANAO to continue the audit through the final stages of the process to the point where the new arrangements for the supply of plasma were in place.

Source: Comments provided by Health to ANAO in July 2003 in response to the section 19 proposed audit report.

1.15 ANAO noted that, as Health did not expect the process for securing plasma and related products beyond the expiry of the PFA to be completed until mid-2004, any audit of the complete process would not be able to be completed until early 2005. Accordingly, in accordance with the JCPAA's request for a timely audit of the PFA extension review, rather than delay reporting to the Parliament, ANAO proceeded with the requested limited scope audit. The audit builds upon previous performance audits undertaken in this area by ANAO.[18]

1.16 Audit fieldwork was undertaken in the BODT[19] between July and September 2002. In addition, fieldwork was also undertaken in the Legal Services

[18] In addition to Audit Report No.24 1999–2000, *Management and Regulation of Plasma Fractionation*, ANAO undertook an earlier audit, Audit Report No.14 1995–96, *Sale of CSL, Commonwealth Blood Product Funding and Regulation*.

[19] At the time that the PFA extension option review was undertaken, the BODT was located within the Health Services Division of Health. Subsequently, the BODT was moved to the Acute Care Division.

Branch of Health in August 2002. Further meetings were held with the Department during the development of the audit report. Meetings were also held with Finance and PM&C in early 2003. ANAO also met with CSL, given its role as a key stakeholder in relation to plasma products.

1.17 ANAO provided four issues papers to Health in December 2002. Following Health's response to these papers in March 2003, ANAO issued a consolidated discussion paper to Health later that month. Health's comments on that paper in April 2003 required ANAO to take legal advice on issues raised by Health relating to section 37 of the *Auditor-General Act 1997* (see paras 1.19–1.24 below for further discussion of this issue). In May 2003, ANAO issued a further discussion paper to Health, which had been revised in light of the Department's comments and ANAO's legal advice. This paper was also provided to Finance and PM&C. In June 2003, the proposed audit report was provided, under section 19 of the *Auditor-General Act 1997* to: the Minister for Health and Ageing; the secretaries of Health, Finance, and PM&C; CSL; Health's and ANAO's legal advisers; and a number of individual officers within Health.

1.18 ANAO engaged the services of Minter Ellison to provide legal advice in relation to a range of issues associated with the PFA extension option and related matters. The audit was conducted in accordance with ANAO Auditing Standards at a cost to the ANAO of $398 000.

Confidentiality of information issues

1.19 Subsection 37(1) of the *Auditor-General Act 1997* provides that the Auditor-General must not include particular information in a public report: if the Auditor-General is of the opinion that disclosure would be contrary to the public interest for any of the reasons set out in subsection 37(2) of the Act; or if the Attorney-General has issued a certificate to the Auditor-General stating that, in the opinion of the Attorney-General, disclosure of the information would be contrary to the public interest for any of the reasons set out in subsection 37(2).

1.20 Subsection 37(2) of the Act states:

> The reasons are:
>
> (a) it would prejudice the security, defence or international relations of the Commonwealth;
>
> (b) it would involve the disclosure of deliberations or decisions of the Cabinet or of a Committee of the Cabinet;
>
> (c) it would prejudice relations between the Commonwealth and a State;
>
> (d) it would divulge any information or matter that was communicated in confidence by the Commonwealth to a State, or a State to the Commonwealth;

(e) it would unfairly prejudice the commercial interests of any body or person;

(f) any other reason that could form the basis for a claim by the Crown in right of the Commonwealth in a judicial proceeding that the information should not be disclosed.

1.21 In April 2003, Health advised ANAO in response to ANAO's March 2003 discussion paper that:

> The Department considers that significant parts of the discussion paper contain material which, having regard to section 37 of the *Auditor-General Act 1997*, should not be included by the Auditor-General in a public report.
>
> The bases for excising parts of the current report fall within the following categories set out in the *Auditor-General Act*:
>
> - publication of details of the PFA is contrary to the commercial interests of the Commonwealth and of CSL (Section 37(2)(e));
> - publication of specified parts of the report would prejudice the Commonwealth's commercial interests in achieving a reasonable commercial outcome in future negotiations with respect to the supply of blood products (section 37(2)(e)); and
> - publication of specified parts of the report would prejudice the proper functioning of the Commonwealth and State governments in achieving public policy outcomes such as safety and continuity of supply of blood products (section 37(2)(f)).

1.22 In response to the issues raised by Health, ANAO took legal advice for the purpose of advising the Auditor-General on the possible circumstances for the application of section 37 of the Act. The summary of that advice was:

> With one exception, assuming the accuracy in factual terms of the ANAO comments, in our opinion, none of the material provided or arguments made by Health would appear to justify a conclusion that section 37 requires the Auditor-General not to include any information about the ANAO comments concerning its five areas of concern in a public report. There are, however, a number of particular comments made by Health that will require examination against section 37, if amendments as suggested by Health are not made.

1.23 ANAO issued a revised discussion paper to Health in May 2003, which took account of this legal advice and the Department's comments on the March 2003 discussion paper. In May 2003, Health further advised ANAO, in response to the revised discussion paper, that it was seeking further deletions under section 37 from the material to be included in the published audit report including statements that the Department considered either breached PFA commercial-in-confidence provisions, or would prejudice future negotiations on plasma fractionation. In July 2003, in response to the section 19 proposed audit report,

Health advised of two additional minor adjustments the Department considered ought be made to the report because of section 37 concerns.

1.24 In preparing the audit report, ANAO had regard to both the legal advice it had received and the various comments it received from Health. While not necessarily accepting the claims raised by Health under section 37 of the Act, the Auditor-General considers that the report no longer contains any material that warrants his consideration under section 37 of the Act and the exclusion of such material does not impact on the conclusions reached in the report.

2. PFA Review Planning

This chapter discusses the background to the PFA extension option review; the National Blood Review; and the initial preparations by Health for the review.

Background

2.1 The May 1994 sale of CSL represented the first 100 per cent public float of shares in a public owned enterprise by the Commonwealth. In this circumstance, ANAO considered it appropriate to conduct a performance audit of the sale. ANAO's objectives in auditing the sale of CSL were to review the extent to which the Government's objectives for the sale were achieved; and to assess ongoing Commonwealth exposures and responsibilities. Audit Report No.14 1995–96, *The Sale of CSL—Commonwealth Blood Product Funding and Regulation*, was tabled on 29 November 1995.

2.2 In addition to examining the management of the sale process and the residual Commonwealth risk exposure as a result of the sale, the audit report also reviewed and made recommendations to improve the then Department of Human Services and Health's [20] administration of payments to CSL under the PFA for plasma products and the Therapeutic Goods Administration's (TGA's) regulation of CSL.[21]

2.3 In light of the importance of the PFA, a further audit of the management of the PFA and TGA's regulation of CSL post-privatisation was undertaken culminating in the tabling of Audit Report No.24 1999–2000 in December 1999. The objectives for the audit were to:

- assess the administrative and financial effectiveness of Health's contract management of the PFA;
- assess whether the TGA's implementation of post sale regulatory arrangements adequately protected the community's interests; and
- assess the extent to which agencies had implemented the recommendations made in Audit Report No.14 1995–96 concerning plasma products funding and regulation of plasma products manufactured under the PFA.

[20] At the time of the 1995–96 audit report, the relevant Commonwealth agency was named the Department of Human Services and Health. Changes to the Administrative Orders have resulted in changes to the department's name over time. For example, at the time of an 1999–2000 audit report, the Department was named the Department of Health and Aged Care while the Department is now known as the Department of Health and Ageing. However, in this audit report, the Department will be referred to as Health.

[21] The TGA within Health is the Commonwealth entity responsible for the regulation of therapeutic goods including the plasma products produced by CSL.

2.4 Among other things, the audit report concluded that there was significant scope for improvement in Health's management practices in relation to the PFA. Marked deficiencies were found in Health's payment control system for more than $400 million in Commonwealth payments under the PFA (made up to 30 June 1999); Health's planning and conduct of commercial negotiations with CSL over price adjustments; and the Department's management of the Commonwealth's exposures under product liability indemnities provided to the company for AIDS and Hepatitis. The Department agreed to all three of the audit report's recommendations, including the recommendation that Health:

- commence early planning for the expiry of the initial term of the PFA contract to ensure that the Commonwealth could advise CSL of its preferred position by May 2002; and
- ensure that, in considering options for future supply of plasma products following the expiry of the initial term of the PFA, the Department sought appropriate expert legal, financial and product advice before entering into any contract negotiations.[22]

JCPAA inquiries

2.5 The JCPAA conducted inquiries into both Audit Report No.14 1995–96 and Audit Report No.24 1999–2000. JCPAA Report No.378 set out the Committee's findings from its inquiry into Audit Report No.24 1999–2000 and made five recommendations building on the work undertaken in the audit report.

2.6 One of the areas of particular concern to the JCPAA related to the audit's findings in relation to Health's handling of the 1996 initial review of the PFA. At the time that the PFA was negotiated and signed in 1993, CSL's Broadmeadows facility was yet to commence full production. Production of plasma products was still largely occurring at the ageing Parkville facility in Melbourne. Accordingly, prices for CSL's plasma products to be supplied under the PFA were costed on the basis of the likely cost structure to apply at the Broadmeadows facility. In negotiating the PFA, both the Commonwealth and CSL recognised that there might be significant variations between the forecast costs and the actual costs of production. In this circumstance, the PFA provided for a review of the cost structure of the operations of the Broadmeadows facility to be commenced as soon as possible after 1 January 1996.

2.7 The initial review was to be undertaken by an independent expert appointed by both parties. The PFA provided that, at the conclusion of the initial review, prices under the PFA were to be adjusted either up or down, taking into account 50 per cent of the difference between the forecast costs and the actual

[22] See Recommendation No.2, Audit Report No.24 *Commonwealth Management and Regulation of Plasma Fractionation.*

costs as determined by the independent expert. The PFA also provided that the independent expert was to review CSL's costs for the 1995 calendar year; provide evidence of the reasonableness of these costs; and, if necessary, adjust the price schedule. The expert's decision was to be binding on both the Department and CSL.

2.8 ANAO's legal advice[23] was that the review process actually undertaken for the 1996 initial review of the PFA was not in accordance with the requirements stipulated in the PFA. The review process outlined by the PFA is in the nature of an arbitration. The process actually undertaken by the consultants, with Health's agreement, was in the nature of a mediation. That is, at a critical point in the process, the reviewer depended on a negotiated outcome between the parties. At no time during the initial review of CSL's cost structure and prices for products supplied under the PFA, did Health obtain legal, accounting or professional industry expert assistance of any kind to inform its negotiation with CSL to deal with the extremely complex commercial and technical issues involved.

2.9 During the 1999–2000 audit, Health advised ANAO that it had calculated the possible outcomes to the negotiation of the issues identified by the reviewer as requiring resolution. These ranged from, at one extreme (acceptance by the Commonwealth of all CSL's claims for increased costs), an increase in annual Commonwealth outlays of $5.8 million or 7.4 per cent for the 1995 level of products to, the other extreme (rejection by the Commonwealth of all of CSL's claims), resulting in a decrease in annual outlays of $1.4 million. Health advised ANAO that 'the Department's view is that an outcome in the middle of the range of likely outcomes represents a reasonable outcome in the circumstances'.

2.10 The JCPAA commented in its Report 378 that:

> The Committee finds it difficult to share [Health's] satisfaction with its achievement of agreed cost increases at the mid-point of the range of potential outcomes. It is noted that the outcome was the second highest outcome of the options identified by the Department in its *comparison of possible outcomes* table. The Committee would have had more confidence in the rejection or acceptance of a claim if it had been based on the expert evidence intended to be provided under the review. It would also have had a basis for accepting [Health's] arguments if evidence in the form of written reasons for accepting the claims had been documented.
>
> While the Committee acknowledges that the PFA contract may have had shortcomings, the lack of appreciation of the size and complexity of the process to be undertaken is unparalleled. While it is not unusual for the parties to contracts to resolve ambiguities by agreement, it is crucial that the Commonwealth have available appropriate expert advice to inform significant financial negotiations.

[23] ANAO's legal adviser for the 1999–2000 audit was the Australian Government Solicitor.

> Without the benefit of any legal, accounting or expert assistance to inform its negotiations with CSL, the Committee considers that the Commonwealth had insufficient information available to it when it entered into the review process.
>
> On that basis, the Committee contends that it is not possible to ascertain whether the Commonwealth's outcome was poor or indifferent. What the Committee is more certain of, given the under-preparedness of [Health] and the woeful history of contract management generally in the public sector, is that the conditions which might have led to a good outcome for the Commonwealth were not present.[24]

2.11 It was in this context that the JCPAA recommended that ANAO undertake a timely performance audit of Health's handling of the review to decide on whether or not the Commonwealth should exercise its unilateral option to extend the PFA on existing terms and conditions.[25]

Blood Review

2.12 The PFA underpins the supply within Australia of healthcare products manufactured by CSL from plasma collected by the ARCBS from volunteer Australian donors. However, the PFA and these plasma products are only one component of the wider Australian blood banking and plasma product sector. The context in which the PFA operates is important to any consideration of future arrangements for the supply of plasma products in Australia.

2.13 During the course of the ANAO audit, the then Minister for Health and Aged Care announced the establishment of a review of the Australian blood banking and plasma product sector (the Blood Review). The review was to cover blood collection and banking activities as well as the processing and distribution of blood and blood products. Former Governor-General, the Right Hon Sir Ninian Stephen, headed the Committee charged with conducting the review.[26] The Committee was asked to investigate the capacity of the Australian blood system to maintain the quality and safety of the blood supply into the future and consider ways to increase the supply of essential blood products.

2.14 Two of the Blood Review's terms of reference had particular relevance to the Commonwealth's consideration of whether or not to exercise its option to extend the PFA for a further five years, or possibly longer, after the Contract's expiry on 30 June 2004. These were as follows:

- Consider and report on strategies to increase the supply of plasma products currently in short supply, including a review of the principle of self-

[24] JCPAA Report 378, *Review of Auditor-General's Reports 1999–2000 Second Quarter*, paras 4.50 to 4.52, p. 45.

[25] See Recommendation No.10, JCPAA Report No.378, p. 35.

[26] Sir Ninian Stephen was the Chairman of the Review Committee. The other members of the Committee were the Hon Dame Margaret Guilfoyle; Professor Robert Beal; and Professor Judith Whitworth.

sufficiency and consideration of the consequences of sourcing additional product from overseas suppliers.

- Assess the economic and productive capacity of the Australian plasma fractionation industry to balance future domestic needs against export opportunities. After taking due note of any safety implications, recommend, if required, strategies to improve that capacity.[27]

2.15 The then Minister's 10 May 1999 press release announcing the Blood Review stated that the review was expected to run for about a year. However, in light of the scale and complexity of the task, the Review Committee's report was not finalised until March 2001.

Blood Review findings and recommendations

2.16 The Blood Review found, overall, that ensuring access to a safe, secure and affordable supply of blood and blood products and ensuring their appropriate use are important public health matters. Accordingly, the Blood Review recommended that, to meet Australia's needs, there should be a national approach to the supply of blood and blood products that delivers efficient and effective services; responds promptly to new and emerging developments; and develops responsible and responsive policies. Central to this national approach was the recommendation of the Blood Review that a National Blood Authority be established, as a priority, to provide national management and oversight of Australia's blood supply.

2.17 The Blood Review recommended that the National Blood Authority be jointly funded by the Commonwealth and State and Territory Governments and its role should include:

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[27] The remaining terms of reference for the Review were as follows.

- Examine and report on the safety and quality of the production and supply of blood and blood products for use in the Australian health care system. If impediments exist to attaining or maintaining safety and quality at best-practice standards recommend strategies to bring about sustainable improvements, including mandatory compliance with a national quality assurance program.
- Taking account of the various reviews of aspects of the blood system currently under way, recommend how the system might best be drawn together to ensure it meets Australia's needs into the future.
- Consider and recommend ways to improve system-wide decision-making processes, including the provision of timely, expert advice on the safety, quality and supply issues that arise from time to time. Among other things the advice should cover:
  - the need for and financial impact of new testing procedures and new products;
  - legal and ethical issues where access to products may have to be based on clinical priorities;
  - cost-effectiveness of proposed safety improvements;
  - the role of an expert reference laboratory in setting and maintaining a national quality assurance program; and
  - the impact of change on public confidence in the blood supply.

- managing and planning Australia's blood and blood product supply to meet current and future needs;
- developing and implementing national contingency planning to manage supply risks;
- administering service delivery and funding arrangements established between the Commonwealth, on behalf of the State, Territory and Commonwealth Governments, and providers of blood and blood products and related services;
- managing and accounting for public funds provided for the national blood supply; and
- monitoring and assessing local and international markets and developments in the sector.[28]

2.18 The Blood Review made the following specific findings in relation to plasma fractionation:

> Australia's future plasma fractionation needs are best met through the national facility operated by CSL. This should be managed through some form of contract similar to the Plasma Fractionation Agreement. The national imperative is that Australia's needs for plasma products are met and that CSL's fractionation of foreign plasma does not pose any significant risks to the safety and quality of domestic products and to product recipients. Clear lines of responsibility and accountability, and performance monitoring, reporting and review, should be incorporated into the Agreement.
>
> Supply arrangements should enable systematic consideration of new product developments and innovations in patient care. Plasma products and their substitutes should be considered in the same way as other therapeutic goods marketed in Australia. Australian governments should seek expert advice on the potential place and costs of new plasma products and substitutes in the Australian supply from the Pharmaceutical Benefits Advisory Committee. Some supporting legislative and regulatory changes are required.
>
> Future arrangements for the manufacture and supply of a range of diagnostic products for blood testing, typing and cross-matching made by CSL from human blood supplied by the ARCBS also need to be considered.[29]

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[28] In addition, the Blood Review recommended that the National Blood Authority identify information needs and priorities for the sector and provide a national focus for performance monitoring and reporting; assist in identifying research needs and priorities with the National Health and Medical Research Council and others; and make recommendations and reports to governments on blood supply matters. (See Summary of Recommendations, *Review of Australian Blood Banking and Plasma Product Sector*, March 2001, p. xiv.)

[29] Executive Summary, *Review of the Australian Blood Banking and Plasma Product Sector*, March 2001, pp. xii–xiii.

2.19 The Blood Review Committee's report was provided to the Government in March 2001. The Blood Review Report recommended, amongst other things, that:

- self-sufficiency should remain an important national goal for Australia—recognising that it is a national and international obligation and responsibility but that the Commonwealth Government should monitor the goal's appropriateness, relevance and application in light of scientific, technological and other developments in transfusion medicine and patient care; and
- the Commonwealth Government should enter into a second Plasma Fractionation Agreement with CSL with a shorter term than the current one and the new National Blood Authority should administer the Plasma Fractionation Agreement as part of national supply planning.[30]

2.20 On 8 June 2001, the then Minister for Health and Aged Care released the Blood Review report stating that 'in response to the Blood Review, the Government will undertake detailed consultations with States and Territories, the Australian Red Cross Blood Service, donors, consumers and other groups to develop a detailed implementation plan for the Review's proposals.'[31]

2.21 Subsequently, on 28 September 2001, the then Minister further announced that the decision by all Australian Health Ministers to accept the recommendation of the Blood Review to establish a National Blood Authority.[32] Under this model for managing the blood sector, there will be a collaborative partnership between the Commonwealth and the States through the National Blood Authority to draw together national blood supply planning and management within one organisation. The *National Blood Authority Act 2003* received royal assent on 15 April 2003. The new authority commenced operations from 1 July 2003 and, accordingly, took over management of the PFA.

Initial preparations by the Department

2.22 Recommendation No.2(b) of Audit Report No.24 1999–2000, tabled in December 1999, recommended the Department commence early planning for the expiry of the initial term of the PFA to ensure that the Commonwealth was in a position to advise CSL of the Commonwealth's preferred position by May 2002. This recommendation followed the 10 May 1999 announcement of the Blood Review.

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30 ibid., pp. xix–xx.

31 Media Release MW49/01 8 June 2001, Dr Michael Wooldridge, Minister for Health and Aged Care.

32 Media Release MW97/01 28 September 2001, Dr Michael Woodridge, Minister for Health and Aged Care.

2.23 Until February 2000, a small section within a branch in the Health Services Division was responsible for the management of the blood and blood products sector, including the various blood programs and the Commonwealth's contracts with CSL. In response to the matters raised in Audit Report No.24 1999–2000 tabled on 22 December 1999, and to provide for dealing with the consequences of the Blood Review, Health established the BODT in February 2000 as a separate branch.

2.24 The BODT initially comprised 11 officers and was given responsibility for: managing the contracts with CSL; planning and policy setting for the blood sector; positioning the Department for future negotiations with CSL; and dealing with the consequences of the Blood Review. At the JCPAA's hearing on 16 May 2000 for the Committee's Inquiry into Audit Report No.24 1999–2000, the Department informed the JCPAA that further resources would be made available to the BODT after the completion of the Blood Review, which was, at that time, expected to be finalised in July 2000. Health advised ANAO that, in establishing the BODT, the Department aimed to directly address the issues identified by ANAO and the JCPAA, and ensure that the Department's management of the sector substantially improved.[33]

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[33] Health further advised ANAO that it established the BODT to:

- provide a dedicated focus to the management and review of issues related to the blood and organ donation sector;
- identify key policy issues for the sector and work with sector stakeholders in defining and implementing sector-wide improvements;
- manage the complex stakeholder relationships and improve the exchange of information throughout the sector;
- provide Commonwealth representation and input to sector developments;
- provide timely and effective administrative and financial management of issues related to the sector;
- undertake regular monitoring and evaluation of program areas;
- develop and implement adequate financial monitoring and payment systems including appropriate reconciliation strategies;
- as required, engage expert legal, accounting, technical and economic advice on complex matters related to the sector using formal processes of engagement;
- improve transparency and accountability of sector activities and implement stringent risk management practices;
- liaise with the Therapeutic Goods Administration (TGA) in the development, implementation and maintenance of world standards for regulation;
- maintain adequate and up-to-date departmental records and implement appropriate practices to ensure compliance with relevant legislation and governmental procedures;
- ensure that staff have adequate skills and training to undertake tasks and activities to a high standard; and
- prepare the Commonwealth's response to the Blood Review.

Consultancy studies

2.25 In March 2000, the BODT engaged a consultant to provide advice regarding the current tasks and issues in the blood program.[34]

> This paper aims to identify tasks and issues that need to be addressed by the Department relating to current blood program responsibilities and to include a work plan to tackle at least some of them. It does so in the context of the National Review of the Blood Sector, which is due to be completed at the end of July 2000. The Department has recognised that there are important tasks to be addressed which cannot wait until the outcomes of the Review are known, and that additional resources are needed by the Blood and Organ Donation Task Force of the Department to address them.

2.26 The consultant's paper specifically noted the requirement to make the decision on the extension option of the PFA by 23 June 2002. The consultant advised the BODT that, 'given the significance of this Agreement, even at this early stage, it is worth developing a project plan as to how the Agreement should be reviewed.' The consultant also noted that 'a Steering Committee would seem appropriate, with external representation from Treasury or [the Department of Finance and Administration].' In relation to the PFA, the consultant suggested he should assist the Department by participating in the development of a project plan by 1 August 2000. A further contract was signed on 3 April 2000 providing for the consultant to undertake this activity along with a range of other services for the BODT and the Blood Review.[35]

2.27 The consultant provided the Department with an initial suggestion for a project plan in July 2000. The draft project plan noted that there was some expectation from the JCPAA that planning for the review of the PFA should already be commencing.

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[34] Specifically, the 14 March 2000 contract provided that: *The Department of Health and Aged Care ('Department') is prepared to accept your proposal to provide Services in relation to producing a paper that specifies discrete tasks to be undertaken for the Health Services Division relating to the administration and management of current blood program responsibilities but in the context of the National Review of the Blood Sector currently underway on the terms and conditions set out below and attached to this letter.*

Services

The contractor will:

1. Undertake a scoping study based on an analysis of a range of reports and documents and consultation with key departmental staff and professionals working within the blood industry; and
2. Produce a paper that will outline the critical issues for the department with respect to:

   Some discrete tasks and outstanding issues which need to be addressed related to current blood program responsibilities; and

   Positioning of the department in managing the outcomes from the Blood Review.

[35] For example the consultant also prepared a paper on contract management in the BODT and undertook work in connection with the review of a separate contract with CSL for the provision of anti-venoms.

2.28 In light of the extent of annual Commonwealth expenditure under the PFA, more than $112 million at the time in 1999–2000, the draft project plan suggested it was 'important to establish a high level committee to oversee the agreement review. It arguably could comprise [the relevant Deputy Secretary and First Assistant Secretary of Health and the National Manager of the TGA], a nominee of PM&C and a nominee of DOFA [Finance]'. In addition, the draft project plan indicated that this Steering Committee should be supported by a secretariat sourced from the BODT and have access to financial, legal, clinical and technical industry expertise.

2.29 The draft project plan suggested that it was probably appropriate that the Steering Committee begin its consideration when the Blood Review had finished its work but that, given the concerns of the JCPAA, it might make sense to at least seek nominations from Finance and PM&C immediately, so that the Committee would be ready to meet in the near future. In addition, the draft project plan advised that the Minister should also be advised of the approach to be taken in looking at future contractual arrangements. The draft project plan set out the steps for the review and a timetable for them. Under the suggested timetable, the initial meeting of the Steering Committee was to occur in October 2000 at which, among other things, the Committee could consider the findings of the Blood Review with particular reference to plasma fractionation. The suggested timetable envisaged advice to the Minister and Cabinet on the extension or otherwise of the PFA being provided by February-March 2002.

2.30 The timetable for the PFA extension review set out in the draft project plan was predicated on the assumption that the report of the Blood Review would be available soon after July 2000. In the event, the Blood Review did not report to the Government until March 2001, delaying any action to finalise and implement the draft project plan.

Blood Review Consultants

2.31 The Blood Review Committee engaged, through a tender process, consultants to provide it with advice in relation to the Australian plasma fractionation and diagnostic products industries. The major report these consultants provided to the Blood Review was a paper dated 30 August 2000, *Review of the economic characteristics of the Australian Plasma Fractionation Industry*. The consultants provided other papers to the Blood Review, including papers in December 2000 and January 2001 that provided strategic advice for the conduct of the PFA extension review and the potential negotiation of a new PFA contract with CSL. In particular, strategies were suggested for addressing the information asymmetry the Commonwealth has in its dealing with CSL.

2.32 These consultants also met with Departmental staff, in December 2000, ahead of the Blood Review's report in March 2001. They gave the Department a presentation on their work.[36] In May 2001, the consultants undertook work for the BODT in relation to the renegotiation of the separate contract with CSL for anti-venoms.[37] Then, in August 2001, the consultants provided to the BODT an unsolicited paper that was a proposed work plan to build up the Department's understanding of the business environment facing CSL with the aim of enabling it to reach an informed decision on whether or not the existing PFA should be extended. No further action appears to have been taken by the Department in relation to the proposed work plan until it was considered during the Steering Committee process, eventually commenced by the Department in December 2001.

[36] The consultants also participated in a contract review group that was established as part of the initial governance structure for the PFA extension review on the advice of the first consultant engaged by the BODT. This contract review group met twice, on 24 January 2001 and on 7 March 2001, and then did not meet again.

[37] On 26 July 2001, the consultants advised the BODT during a meeting that, three weeks earlier, CSL, had contacted the consultants asking if they were in a position to undertake work for the company. The consultants advised the BODT that they had made it clear at that time that they would not be able to work for CSL given their ongoing work for the Department. The consultants were not approached to undertake further work for Health until March 2002, during the Steering Committee process. When approached at this time, the consultants advised that they were not in a position to accept work from the Department as the consultants had accepted an offer of work from CSL and a conflict of interest would occur should they also work for the Department.

3. Review Evaluation Framework

This chapter outlines Health's Steering Committee process undertaken for the PFA extension option review; the main position paper prepared to inform the Steering Committee's decision; and the decision of the Steering Committee. In addition, the issue of consultation with CSL is addressed.

Departmental Steering Committee process

3.1 Health was aware from the signing of the Contract on 23 December 1993 of the requirement that the Commonwealth be in a position to notify CSL by 23 June 2002 of its decision whether or not to exercise its option to extend the PFA. The need for early planning to ensure that the Department was in a position to advise the Government on the option in a timely manner prior to the expiry of the option was further highlighted by the recommendation to this effect in Audit Report No.24 1999–2000 tabled in December 1999.

3.2 In the event, the Steering Committee process for determining Health's recommendation to the Government on the PFA extension option commenced in December 2001. The four-person *Steering Committee for the Future of Plasma Fractionation and Diagnostic Products Arrangements* was comprised of Senior Executive Service officers from the Department, including from the TGA. The high level Steering Committee was charged with the responsibility of advising the Government on future arrangements for plasma fractionation and diagnostic products, including whether the Commonwealth should exercise its unilateral option to extend the PFA for five years, or possibly longer.

3.3 In May 2003, Health advised ANAO that:

> ANAO appears to be making an artificial distinction between the extensive planning, preparatory and review work undertaken by the Department between 1999 and December 2001 and the time taken by the Steering Committee to consider the issues.

3.4 Additional staff were recruited into the BODT in late 2001 to provide the resources both for a secretariat to support the Steering Committee and also to undertake other work on the implementation of the Blood Review recommendations. In March 2001, the BODT was comprised of 20 officers.[38] As at March 2002, 40 officers were employed in the BODT.

3.5 To develop Health's recommendation on the PFA extension option, the Steering Committee adopted a process involving:

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[38] This staffing profile included two consultants who were providing financial advice and related assistance to support the work of the BODT.

- consideration of the findings and recommendations of the Blood Review[39] relating to the future supply of plasma products;
- review of the expert advice provided to the Blood Review in relation to the plasma fractionation industry;
- commissioning and reviewing a range of relevant papers prepared by the BODT, or consultants engaged by the BODT, in its role as secretariat to the Steering Committee; and
- considering separate opinions requested by the Steering Committee from a legal adviser and the BODT's economic consultant on the final paper prepared for the Steering Committee.[40]

3.6 The BODT provided a secretariat for the Steering Committee and was responsible for producing a range of agenda papers for consideration by the Steering Committee and for coordinating the advice from an economic adviser and a legal adviser engaged to provide assistance to the Steering Committee process.

3.7 The first meeting of the Steering Committee occurred on 14 December 2001. At this meeting, the Steering Committee approved, as amended, draft terms of reference for its work that had been prepared by the BODT. In total, the Steering Committee met four times before reaching a decision on its recommendation regarding the extension option contained in the PFA.

3.8 At its second meeting on 1 February 2002, the Steering Committee agreed that the overarching objective for future plasma fractionation arrangements

[39] The relevant recommendations of the March 2001 Blood Review Report were:
- Self-sufficiency should remain an important national goal for Australia recognising that it is a national and international obligation and responsibility but that the Commonwealth Government should monitor the goal's appropriateness, relevance and application in light of scientific, technological and other developments in transfusion medicine and patient care.
- The Commonwealth Government should enter into a second Plasma Fractionation Agreement with CSL at the expiry of the first ten and a half years of the present agreement (at 30 June 2004) to ensure that Australia's future needs for plasma products are met.
- The Agreement should be for a shorter term than the current one.
- The new National Blood Authority should administer the Plasma Fractionation Agreement as part of national supply planning.
- The National Blood Authority should report regularly to Australian Health Ministers on progress with the administration of the Agreement and outcomes.

[40] The assignment of the two consultants was to provide written comments for the Steering Committee on the recommendation being put to the Steering Committee and the supporting papers in relation to:
- the appropriateness of the risk analysis method applied;
- the application of the method to the PFA extension option;
- the apparent comprehensiveness of the determination of risks;
- the validity of the conclusions drawn (assuming the risk determination is accurate); and
- other comments deemed germane for the committee to consider in the specific context of the risks of exercising the extension option

would be 'an adequate, safe, affordable and secure supply of plasma products in Australia'. The Committee accepted further detailed objectives identified under this overarching objective as forming the framework in which the overarching objective would be achieved. At the fourth Steering Committee meeting on 18 April 2002, two months before the option expired, the Committee reached the decision that it should recommend to the Government that the option to extend the PFA not be exercised.

3.9 In recommending the Government enter into a second PFA with CSL at the expiry of the present agreement, the Blood Review noted that it supported 'the establishment of a new, shorter-term plasma fractionation agreement rather than an extension of the current one.'[41] Health advised ANAO in July 2003 that:

> The Blood Review was the most comprehensive review of the Australian blood sector ever undertaken. The Blood Review Committee comprised eminent and expert Australians who evaluated submissions and testimony from most, if not all, the key players in the blood sector. The Review also commissioned reports from economic and industry experts to aid its consideration of Australia's future plasma fractionation requirements and the changes that were occurring in the clinical use of plasma products and their substitutes. The Blood Review Committee was unequivocal in its view that the current PFA was an historic, foundation agreement that had served its purpose and should not be extended. Notwithstanding advice from the BODT that the Blood review did not consider in detail the option to extend the PFA, the Steering Committee placed a good deal of weight on the conclusions and recommendations of the Blood Review Committee because of the breadth of its analysis and direct relevance of its plasma product findings to its own considerations.

3.10 ANAO notes that the Blood Review was unequivocal in its view that the PFA should not be extended. However, during the Steering Committee's deliberations in April 2002 on the PFA extension option, the BODT advised the Steering Committee that, in recommending the establishment of a new, shorter-term agreement between the Commonwealth and CSL, the Blood Review did not consider in detail the option to extend the PFA(see paras 8–9 in the Summary for further comment).[42]

BODT Position Paper

3.11 In the agenda paper prepared by the BODT for the 18 April 2002 Steering Committee meeting, which recommended that the Commonwealth not exercise the option to extend the PFA, the Steering Committee was advised that the

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[41] ibid., p. 89.

[42] Paragraphs 4.3 to 4.5 of the agenda paper prepared by the BODT for Item 2 of the Steering Committee's agenda for its 18 April 2002 meeting.

current PFA had a range of disadvantages. The Steering Committee was also advised that major risks of exercising the extension option were *inter alia*:

- not being able to replace the now outdated objective of underpinning a successful sale of CSL with a more appropriate and relevant set of objectives; and
- being unable to demonstrate the Commonwealth is achieving value for money.

3.12 Given the deficiencies it had identified in the PFA and the risks it considered were associated with extending it, the BODT's agenda paper advised the Committee that a decision to extend the PFA would only be exercised where there were substantial risks of the Commonwealth not meeting its objectives in terms of ensuring that an adequate, safe and secure supply of plasma products were available to the Australian community at an affordable and competitive cost.

3.13 The BODT's paper concluded that balanced against the disadvantages and risks of the current PFA, there was no strong evidence to expect a cost benefit to the Commonwealth from extending the PFA. The paper argued that it was reasonable to conclude that the Commonwealth would be able to negotiate a value for money price for plasma products as new supply planning, conservation and pricing methods are implemented. CSL had previously provided information that Australian prices for plasma products averaged 75 per cent of prices in major European markets and 64 per cent of the prices available from commercial sources, noting that collection systems and prices vary across countries. Price information about plasma products is difficult to obtain as it is generally considered commercial in confidence information. Following the decision on the PFA extension option, Health has commenced work to secure additional information on international prices for plasma products.

Supply considerations

3.14 The BODT's paper for the 18 April 2002 Steering Committee meeting also concluded that there was no reason to consider that there would be a quality or safety benefit from extending the PFA given the separate, strict, regulatory regime administered by the TGA in Australia and that CSL's compliance with the regime is recognised by the Commonwealth and CSL as non-negotiable. The paper concluded that there should be no difficulty in continuing to deal adequately with quality and safety issues if the PFA were not extended.

3.15 The BODT's paper noted that Australia represents less than 1 per cent of the international fractionation market in which the United States is dominant,

producing 60 per cent of the world's supply. The paper also noted that there is excess capacity internationally. The paper recognised that, through the current PFA, continuity and security of supply of plasma products in Australia was achieved for a 10 and a half-year period. The Blood Review considered Australian self-sufficiency in products derived from human blood and plasma remains a relevant and appropriate goal for securing Australia's future blood and blood product needs, but that this should be kept under review.

Steering Committee's decision

3.16 Health's Steering Committee determined that it could make a decision on the PFA extension option prior to substantive work being undertaken on the costs and benefits of alternative options for the future supply of plasma products or the identification of a preferred option. The Committee concluded that it had sufficient information before it, through the processes it had undertaken, to make the decision in regard to the PFA extension option. The Committee reached this conclusion notwithstanding that it had yet to commission work to underpin future advice to the Government on how the Commonwealth should secure the national supply of plasma products post the expiry of the PFA on 30 June 2004.

3.17 The Committee resolved at its 18 April 2002 meeting that it should recommend to the Government that the PFA extension option not be exercised and that work should subsequently commence immediately on the development of the Committee's recommendation to the Government on the future arrangements for plasma fractionation following the expiry of the PFA on 30 June 2004.

3.18 The Committee's record of its 18 April 2002 decision on the PFA extension option sets out the main grounds for its decision. The Committee considered that the main advantages of extending the current PFA were: continuity of supply would be assured; arrangements with CSL could be handed over by the Commonwealth to a new National Blood Authority on an 'as is' basis; and there was no requirement for a major administrative effort to reach new supply arrangements.

3.19 The Committee considered the main disadvantages of extending the PFA were:

- the current pricing arrangements were unlikely to be the most advantageous available to the Commonwealth;
- the current PFA .....[guarantees].....CSL revenue must be no less than the revenue received in a previous year; and

- the current PFA is particularly disadvantageous to the Commonwealth in relation to changes in the mix of products and the addition of new product lines, both likely to be important requirements over the next five to ten years.

3.20 At the Steering Committee's 18 April 2002 meeting, the Committee resolved to advise the Government not to exercise the option to extend the PFA for five years or longer post 30 June 2004. On 1 May 2002, the then Chair of the Steering Committee signed a record of decision recording this. The then Chair's record of decision set out the method used to reach the decision, the main grounds for the decision, and the Committee's conclusion.

3.21 The Committee noted that the objective of Government support for plasma fractionation arrangements in Australia was an adequate, safe, affordable and secure supply of plasma products in Australia. The Committee also noted the underlying framework it had developed for achieving this objective and a copy of this framework was attached to the then Chair's record of decision.

3.22 The record of decision stated that over a number of meetings the Committee sought to provide itself with sufficient information on which to base a decision on the question of whether or not to extend the PFA. The Committee also reviewed the findings and recommendations of the Blood Review; requested papers on the advantages and disadvantages of the current PFA arrangements; reviewed and agreed risk analyses relating to the options of extending and not extending the PFA; commissioned an analysis of CSL's business position; and commissioned two independent opinions on the risk analyses undertaken and the potential conclusions to be drawn from some of these materials. A list of materials the Committee had available to it as a result of this work was attached to the record of decision.

3.23 The Committee recorded that it considered that, at the meeting on 18 April 2002, it had before it sufficient information to reach a decision. The Committee considered that the main risk with not extending the PFA was the risk that the Department could not organise itself effectively and on time to achieve the optimum new supply arrangements.

3.24 In light of these considerations, the Committee concluded that the disadvantages of extending the current PFA outweighed the advantages. The Committee also asked that work needed to be done as a priority to manage the risks associated with the decision not to extend.

Consultation with CSL

3.25 In reaching its conclusions about extending the PFA, at no time did the Steering Committee or the Department consult with CSL about the PFA extension option. Health advised ANAO in May 2003 that:

> The Steering Committee concluded that there were major disadvantages with the current PFA. Some of these were in relation to emerging issues that would have their full impact in a new contract period. In the circumstances, the major changes required by the Commonwealth to rectify these disadvantages were not consistent with the extension option. The Committee concluded that a completely new contract would be required. Once it was clear that extension was not a viable option, the Steering Committee chose not to approach CSL so that any future negotiations would be conducted on equal terms. The Department did, however, conclude a contract variation with CSL in January 2003 to address issues of more immediate management and operational concern.

3.26 ANAO notes that, when major contracts incorporate an option to extend the contract, it would be unusual for the parties not to attempt to consult to inform themselves about the pros and cons of exercising that option prior to its expiry. Any contract involving long term supply arrangements in an environment of change will generally require some amendment to keep it relevant over time. As outlined above, Health advised ANAO in May 2003 that it has concluded a contract variation with CSL post the expiry of the PFA extension option.

3.27 In the ANAO's view, effective communication between the parties is a prerequisite to good contract management both for ongoing operations and for strategic purposes. The absence of dialogue in relation to the strategic management of an important Commonwealth contract is, in ANAO's experience, unusual, particularly given Health's advice to ANAO that the cost involved for the supply of plasma products in the five years following the expiry of the PFA could be in the order of some hundreds of millions of dollars.

3.28 In response to ANAO's May 2003 discussion paper, Health advised that:

> It is necessary to distinguish between discussions with CSL on the extension issues beyond 30 June 2004 and dialogue on other issues relating to strategic management and operational matters. There is very good communication between Health and CSL on both day to day and strategic issues, including the need to update the contract from time to time to reflect changing circumstances. For example, in January 2003, the parties executed a deed of contract to amend several aspects of the PFA so that it better reflected changing operational requirements.

3.29 In response to the section 19 proposed report, CSL advised ANAO that:

> The matter of extending the current PFA was considered, albeit indirectly, by the Stephen Committee in the Review of the Australian Blood Banking and Plasma

Product Sector [that is, the Blood Review chaired by Sir Ninian Stephen]. In their Report, released in June 2001, one of the Stephen Committee's recommendations associated with the Australian plasma fractionation industry was for the Commonwealth Government to enter into a second PFA with CSL at the expiry of the present agreement (at 30 June 2004).

On the basis of this recommendation from the Stephen Review, CSL had anticipated that it would be unlikely for the Commonwealth Government to move forward with the option to extend the existing PFA until 30 June 2009.

The ANAO Report outlines the lack of effective communication between [Health] and CSL for 'ongoing operations and for strategic purposes'. With the exception of this issue, CSL considers the level of consultation and communication with in particular the Blood & Organ Donation Taskforce, and recently with the National Blood Authority, to be appropriate. Several communication channels have been established between [Health] and CSL across a broad spectrum of operational and strategic issues involving staff from different levels of both organizations.

In addition, over the last 18 months, two important tripartite forums have been established which include not only senior staff of [Health] and CSL, but also the Australian Red Cross Blood Service. These forums have become an important vehicle in effective operational and strategic planning for the provision of plasma products in Australia.

4. Process Outcome

This chapter examines the outcome of the extension option review process including in terms of the adequacy of the value for money assessment and the timeliness of the process. The chapter also outlines the process and timing of the advice to the Government on the extension option review outcome. In addition, the chapter addresses the general issue that arose in the audit in relation to major procurement contract options.

Value for money

4.1 The CPGs state that value for money is the core principle governing Commonwealth procurement.[43] In addition, the FMA Act places the obligation on Chief Executives to promote proper (efficient and effective) use of Commonwealth resources. Application of the CPGs and the requirements of section 44 of the FMA Act, require that an important step in establishing the value for money of the PFA extension option would involve establishing the costs and benefits of alternative options for obtaining plasma products after the expiry of the PFA on 30 June 2004, relative to the costs and benefits of an extended PFA. Indeed, on 18 April 2002, the legal adviser commissioned by the Steering Committee to provide it with an opinion on the papers prepared by the BODT advised the Committee that:

> Having confirmed the key objective of the Commonwealth, we suggest that the central issue to consider with respect to the decision whether to extend the PFA is whether the Committee considers the Commonwealth can negotiate a better deal than the existing one, having regard to the objective/s referred to above.[44]

4.2 Under the PFA a two-tier pricing system applies where the higher tier-one price is paid by the Commonwealth on a threshold level for each product that is broadly in line with CSL's production levels at the time the PFA was signed in late 1993. The second-tier price, which is significantly lower than the first-tier price, is paid on all production above the threshold level and aims to recover CSL's variable costs.[45]

4.3 The amount of plasma products CSL is able to produce is driven by the availability of plasma to process into the various products. The volume of plasma

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[43] This core principle is underpinned by four supporting principles:
- efficiency and effectiveness;
- accountability and transparency;
- ethics; and
- industry development.

[44] That is an adequate, safe, affordable and secure supply of plasma products in Australia.

[45] See CSL Limited Prospectus, April 1994, p. 84 and *Review of the Australian Blood Banking and Plasma Product Sector*, March 2001, p. 88.

provided to CSL by the ARCBS has increased by nearly 50 per cent between 1992–93 and 2001–02[46] and CSL production levels have accordingly increased. Therefore, over the course of the PFA, for those products in most demand an increasing amount of the total volume of product purchased by the Commonwealth has been purchased at the lower tier-two prices.

4.4 In 1995–96, eight products out of the 17 different products then supplied under the PFA exceeded the minimum volume threshold to at least some extent. However, only 5.5 per cent of payments made under the PFA in 1995–96 were for products at the lower tier-two price. By 2001–02, nearly 25 per cent of the total payments in 2001–02 were for products at the lower tier-two price, representing a more than four-fold increase as compared to 1995–96 expenditure.

4.5 The advice provided to the Committee regarding the relative value for money of the PFA extension option was formulated on the basis of analysis of the current contract and preliminary testing of the operation of the contract in response to the likely effects of a number of possible changes to the product mix over the term of the possible PFA extension. It did not involve direct comparison of the relative costs and benefits of extending the PFA to those of alternative options, as the detailed work to identify specific alternative options and assess their costs and benefits was not undertaken prior to the Steering Committee reaching its decision on the option.

4.6 The Steering Committee concluded that the disadvantages of the PFA outweighed the advantages, including the two-tier pricing system. However, ANAO found a lack of detailed work undertaken during the Steering Committee process to clarify the contract's terms, including, analysis of potential for benefits to the Commonwealth from continuation of the existing terms of the two-tier pricing system for plasma products which applies under the PFA. Furthermore, in the absence of detailed work on the costs, benefits and practicality of alternative options to an extended PFA it is not clear that the Committee had available to it sufficient information on the value for money of not extending the PFA as opposed to exercising the option.

4.7 Health advised ANAO in response to ANAO's May 2003 discussion paper that:

> The decision not to extend the existing contract was essentially an evaluation of whether the PFA (developed as part of the sale of an asset, and designed specifically to ensure the smooth transition of the asset from public to private ownership) was still appropriate ten years later when the market had changed significantly.
>
> The Steering Committee was aware of the benefits that are nominally inherent in the two-tier pricing arrangements, particularly as supply increases. However, with

[46] Information provided to ANAO by Health in February and April 2003.

the increasing substitution of plasma coagulation products with their recombinant alternatives and with demand for albumin now fully met for the foreseeable future, PFA costs were unlikely to fall significantly in the future as a result of the two-tier pricing arrangement. The Steering Committee took note of this fact, together with the other disadvantages of extending the PFA, in reaching its decision.

The Steering Committee took the position that the decision not to extend the contract was a point in a continuum of decision making across the much greater range of issues involved in ensuring safe, secure, adequate and affordable supply of blood products in Australia. The Steering Committee concluded it did not have to determine the costs and benefits of alternative supply options before it made a decision on the extension option but that this analysis would be undertaken in the next phase of the process.

4.8 ANAO would have expected that the costs and benefits of alternative options for the future provision of plasma products after the expiry of the PFA would have been explored by Health in advance of making a decision on the PFA extension option in order to make an informed judgement about the value of exercising the option. This was not the case.

4.9 ANAO also notes that no attempt was made, as part of the process to consider the PFA extension option, to negotiate with the other party to the contract, CSL. The Steering Committee concluded that it had sufficient information before it, through the processes it had undertaken, to make the decision in regard to the PFA extension option. However, in ANAO's view, the question remains whether Health's Steering Committee did have sufficient substantive information on the costs and benefits of the option to make an informed recommendation.

4.10 ANAO notes that the CPGs provide that when 'officials buys goods and services they need to be satisfied that the best possible outcome has been achieved taking into account all relevant costs and benefits over the whole of the procurement cycle.' [47] However, ANAO found that there was an absence of analytical work on the costs and benefits of the PFA extension option. Accordingly, in ANAO's view, it is not clear that the decision-maker was provided with sufficient information to make an informed value for money decision on the option (see paragraphs 4.3 to 4.5).

4.11 In any long-term contract in a complex area such as plasma fractionation, particularly one that extends over 10.5 years, change gives rise to difficulties that need to be addressed in a timely fashion. The development of a non-adversarial relationship, which seeks to ameliorate problems at any early stage

[47] *Commonwealth Procurement Guidelines and Better Practice Guidance* (February 2002) see <http://www.finance.gov.au/ctc/publications/purchasing/cpg/commonwealth_procurement_guide.html#Valueformoney>

to the benefit of both parties, can, through effective communication and cooperation, achieve this aim.[48]

4.12 ANAO notes that, at the point of taking the decision not to extend the PFA in June 2002, there was still a further two years before the PFA was due to expire involving expenditure of around $250 million. Health was working with a contract that it had already acknowledged was defective. Health advised in response to ANAO's May 2003 discussion paper that:

> The main disadvantages of the current PFA identified by the Steering Committee in relation to the extension option are summarised in paragraph [3.19]. Some relate to emerging circumstances and are more relevant to a future contract than the present one. Other, more pressing contractual problems have been identified by the Department and ANAO in previous audits. The Department is in constant communication with CSL about the operation and management of the PFA, including the need to amend the contract to address changing circumstances. Following negotiations in the second half of 2002, Health and CSL executed a deed of contract variation in January 2003 that addressed a number of identified contract deficiencies, including new procedures for invoicing and reconciling accounts, enhanced payment procedures, new procedures for adding, modifying or removing products from the approved product list and enhanced accountability requirements.

PFA minimum revenue

4.13 The Steering Committee received legal advice on 18 April 2002, which it relied on in deciding to recommend that the PFA extension option not be exercised. A key part of the legal advice was the proposition that:

> even if the Commonwealth were to source a significantly greater proportion of its requirements outside of the PFA, the revenue received by CSL must be no less than the revenue received for the previous financial year, as indexed under the contract (that is, CSL's revenue would not decline even if it manufactured less product under the PFA).[49]

4.14 The record of the Steering Committee's decision identified this as one of the three main disadvantages of the current PFA.

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[48] Report 379 October 2000 of the Joint Committee of Public Accounts and Audit noted at paragraph 3.81 on p. 80 that:

Appropriate and clearly understood contract specifications are the beginning point. Next is an effective partnering relationship with effective lines of communication, monitoring and feedback. The constant message, in relevant guidelines and Auditor-General performance audits, is a preventative approach in which problems are quickly identified and solutions found.

[49] Health's legal adviser's advice to the Steering Committee of 18 April 2002, p. 3.

4.15 Heath advised ANAO in May 2003 that:

> The legal advice of 18 April 2002 considered the effect of likely changes to the Commonwealth requirements during the option period. It provided that *'These were matters which, if the parties could not agree on price, would be dealt with under clause 3.5 of the agreement and which therefore triggered the provisions relating to expert determination.'*

4.16 ANAO received legal advice that it is not clear that Health's interpretation of the PFA's terms, such that CSL's revenue is not able to fall from that of the previous year, is a correct interpretation of the operation of the PFA.[50] Subsequently, Health obtained advice from the Chief General Counsel at the Australian Government Solicitor (AGS) that conflicted with the earlier advice obtained by ANAO. Consequently, ANAO can only note the differences in legal opinions. However, the legal advice obtained by Health from AGS did conclude that Health's own legal adviser's general statement as to guaranteed revenue overstated the position as to guaranteed revenue because it did not spell out that, in AGS' view, this only happens 'when a certain series of events occurs.'[51]

4.17 In May 2003, Health advised ANAO that:

> The Steering Committee properly sought, and properly took account of, legal advice in reaching its recommendation on the exercise of the option. Further, the legal advice received by the Steering Committee appropriately and correctly

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[50] ANAO's legal advice was that:

> Paragraph 11 of Schedule B (paragraph B11), which *prima facie* has the effect of providing continuity of revenue for CSL Ltd in the PFA in the absence of agreement by the parties to the contrary, is inconsistent with a principal clause of the contract, clause 3.2.6. It is our view that paragraph B11 and the clause probably cannot be construed in a manner to make them consistent, because they require opposite results.
>
> Where there is a conflict between a clause and a term in a Schedule, then the clause prevails (clause 1.2.9).
>
> Subject to a qualification concerning the intention of the parties, which may have to be explored further, we do not think that the inconsistency can be remedied by omitting a word or words from the PFA. As a result, clause 22.2 would have the effect of severing paragraph B11 from the PFA.

[51] AGS' advice to Health of 27 March 2003 was that:

> …in certain circumstances, the effect of the relevant provisions of the BFA (sic) can be that the total revenue received by CSL in a financial year is no less than the revenue received in the previous financial year. This may occur if the Commonwealth notifies CSL that it requires less than the minimum volume of a particular product under the BFA (sic) and a price review is triggered. Whether this is 'extraordinary' from a policy perspective may be one thing, but it cannot be extraordinary if that is what the contract provides. The relevant provision may have been intended to ensure minimum levels of income not existing levels of income, but its terms are not so confined and whether that was the intention is not clear.
>
> I also confirm my earlier advice indicates that while [*Health's Legal Adviser's*] advice overstates the position as to guaranteed revenue, this is because it does not spell out that this only occurs when a certain series of events happens. I confirm the conclusion contained in the [*Legal Adviser's*] advice is not fundamentally incorrect if it is understood as limited to a situation where those series of events occur. I am, of course, in no position to conclude how likely it was that the necessary events would occur and hence whether the unqualified [*Legal Adviser's*] statement reflected, on the basis of predicted purchase models, an almost certain outcome if the contract option to terminate had not been exercised.

highlighted a feature of the PFA which may have significant implications for the Commonwealth, given the likely scenarios for Commonwealth requirements for products under the contract.

The legal advice obtained by Health from AGS did include the comment that the original Health legal adviser's general statement as to guaranteed revenue overstated the position as to guaranteed revenue because it did not spell out that, in AGS' view, this only happens when a certain series of events occurs. Health's view is that this comment is not material. It simply reflects the fact that the relevant series of events was not included in the same paragraph as the proposition on guaranteed revenue. The relevant series of events was, however, clearly identified in the surrounding discussion in the legal advice.

4.18 Under the PFA, a minimum volume is prescribed for each product. The contract provides[52] that where the volume required by the Commonwealth in any year is less than the minimum prescribed by the PFA for a particular plasma product, CSL may seek an adjustment of the unit price for that and/or other products, and the Commonwealth must negotiate with CSL. If the parties cannot agree on a price adjustment, then a pricing review must be undertaken by a suitably qualified independent expert. The expert must conduct the review in accordance with the Terms of Reference set out in Schedule B to the PFA. It is paragraph 11 of Schedule B that provides the income maintenance provision relied on by Health's legal advisers.

4.19 ANAO's legal adviser is of the view that paragraph B11 of the PFA does not apply in the circumstances set out in para 4.13 because it is inconsistent with a clause of the main body of the PFA. ANAO notes that CSL's revenue under the PFA has risen in each year of the contract to date. However, ANAO also notes that there have already been occasions when Health has notified CSL that it required less than the specified minimum volume of a particular product for a year. To date, CSL has yet to seek to use the provisions of the PFA to seek an adjustment to the price of such a product.

4.20 Health advised ANAO in response to its May 2003 discussion paper that:

> There have only been a few occasions where the Commonwealth has requested less than the minimum volume for a product. With one exception this has been for specialised, low volume products where a temporary surplus has developed because of reduced demand. The other instance occurred when an old product was replaced with a new one and demand for the old product reduced significantly, as was expected. These occurrences are materially different to the prospect of sustained and permanent reductions in demand for some products as was contemplated by the Steering Committee.

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[52] Clause 3.2.5 of the PFA.

Timeliness of the process

4.21 At the third meeting of the Steering Committee on 15 March 2002, the Committee considered, among other things, a proposed outline of a paper on feasible options for the provision of plasma fractionation in Australia to be prepared for the Committee's consideration at its April 2002 meeting.

4.22 The Committee decided that :

(a) A paper [should] be prepared exploring the question of whether or not to extend the current Plasma Fractionation Agreement beyond 30 June 2004. The paper is to (i) examine the material prepared for the Review of the Australian Blood Banking and Plasma Products Sector (the Blood Review) and report on the extent to which the above question was addressed and the adequacy of the evidence on which it was based; (ii) set out the legal opinion on the relevant clauses in the PFA regarding options available to the Commonwealth including second counsel; comment on the 'pros and cons' of exercising the option and not exercising the option; (iii) briefly set out the risks of exercising/not exercising the option; and (iv) review whether any material factors have changed since the release of the Blood Review.....

(b) A paper [should] be prepared exploring the options for achieving the overarching objective of ensuring an adequate, safe, affordable and secure supply of plasma products in Australia .....[53]

4.23 The Steering Committee also decided that these papers should be prepared as soon as possible, with the second paper referred to in paragraph (b) to be prepared by the most suitably qualified external consultants available to meet the timeline consistent with value for money. A draft brief for this paper was provided to the Chair of the Steering Committee on 20 March 2002. The draft brief proposed directly engaging the same consultants who had done significant work for the Blood Review including a major report dated 30 August 2000, *Review of the economic characteristics of the Australian Plasma Fractionation Industry*. The time-line for delivery set out in the draft brief was two weeks from signing a contract.

4.24 However, Health's file record of 25 March 2002 notes that, when the Department approached the consultants about their availability to undertake the assignment, the consultants advised that they had accepted an offer of work from CSL Limited. The consultants noted that, therefore, a conflict of interest would occur should the consultants also work for the Department.

4.25 Subsequently, having been advised of the unavailability of the Blood Review consultants, the Steering Committee endorsed at its fourth meeting on 18 April 2002 a revised approach recommended by the BODT. This was the

[53] 3rd Steering Committee Meeting–Final Minutes

same meeting at which the Steering Committee reached its decision to recommend to the Government that the PFA extension option not be exercised. The BODT's revised approach involved undertaking a select tender process for the procurement of an options paper. A revised timeline of some months was therefore proposed for the procurement of the options paper.

4.26 In this circumstance, it seems that a key reason for the Steering Committee not exploring the costs and benefits of alternative options in advance of making a decision on the PFA extension option, was that there was insufficient time available to the Committee to complete this process prior to the expiry of the option on 23 June 2002.

4.27 Health advised ANAO in May 2003 in response to ANAO's May discussion paper that:

> The absence of a paper on options for achieving the Commonwealth's plasma product objectives was not the reason why the Steering Committee did not assess the benefits of alternative supply options before it made its decision. It did receive papers on the topics identified in paragraph [4.22(a)], which were much more relevant to the immediate question of whether or not to extend the PFA.
>
> The Steering Committee formed the view that there was no requirement to make the extension decision concurrently with an assessment of the cost and benefits of alternative supply options. Moreover, the Steering Committee viewed the extension decision, not as an end point in itself, but as part of a continuum to achieve the Commonwealth's objectives of a safe, secure and affordable supply of plasma products. In that context, the assessment of the costs and benefits of alternatives could be left to the next phase of the continuum. What was clear to the Steering Committee at that stage was that there were significant disadvantages in extending the PFA and that, prima facie, other options were preferable in terms of achieving the full range of Commonwealth objectives.

Advice to Government

4.28 At its 18 April 2002 meeting, in addition to reaching the decision to recommend to the Government that the PFA extension option not be exercised, the Steering Committee considered another paper prepared by the BODT on the methods available for advising the Government of this decision. The paper set out two suggested approaches[54]: a Cabinet Submission; or a letter from the Minister for Health and Ageing to the Prime Minister, with copies to the Treasurer and the Minister for Finance and Administration.

4.29 The BODT paper advised that there were advantages in using the Cabinet Submission option for advice to Government as:

- it is an effective process to consult with other relevant Departments, namely PM&C, Finance and the Department of the Treasury; and
- it would provide a comprehensive proposal to the Government and it would be effective in obtaining Commonwealth support.

4.30 However, the paper also noted that there was not a strict need for a Cabinet Submission because the PFA extension option did not fit the criteria set out in the *Cabinet Handbook*. The BODT paper stated the advantages of opting for the Minister to write to the Prime Minister, with a copy of the letter also forwarded to the Treasurer and the Minister for Finance and Administration were that: it permitted high-level consideration and approval; and it allowed a more flexible, shorter approach.

4.31 The BODT paper further advised the Steering Committee that it should note that the critical date for notifying CSL of any extension of the current PFA was 23 June 2002 and that the Government had not been approached by the Department to date with recommendations for future plasma fractionation arrangements except in the context of Government consideration of the Blood Review recommendations. The BODT paper recommended that the Steering Committee agree to advise the Minister that she write to the Prime Minister, with the advice that the option of extending the current PFA not be exercised.

4.32 The minutes of the 18 April 2002 Steering Committee meeting record that the Committee decided that a senior officer from Health would speak with a senior officer from PM&C about the preferred method of progressing this matter through Government. On 20 May 2002, just over a month prior to the expiry of the PFA extension option, the relevant senior officer from Health sent an email to the then Chair of the Steering Committee stating:

> I also have verbal advice from PM&C that they would not expect the Minister to go to Cabinet on the PFA extension option. The way forward appears to be a letter from [the Minister] to [the Prime Minister], cc [Minister for Finance and Administration] and possibly Minister for Industry. This is because there is no substantive policy change and no direct budget implication nor very substantial budget risk. I am following up again to have confirmed but see no need to have in writing—this could take far too long. I'll do a file note. Then we will have to move smartly.

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[54] In offering these two suggestions the BODT paper noted:

One of the criticisms of the ANAO of the current PFA was that, at the time of negotiating the agreement, the Department did not provide a documented briefing to the Minister or raise the issue with Cabinet prior to its execution. Given the importance of the PFA and previous Parliamentary scrutiny, it is considered essential to enable Government to consider and decide on whether or not to exercise the option to extend the PFA.

4.33 On 23 May 2002, Health received an email from the relevant officer in PM&C advising:

> Further to our conversation last week on CSL. I think there is a need to get more details on this quickly. The deadline of 23 June 2002 for advising CSL is approaching fast and I am not in a position to identify, as you requested, a process for resolving the question of whether or not to extend the contract without further information on the risks, benefits and alternative options.
>
> There are potentially significant implications with not extending the contract and I would like to see further details before determining whether or not this is an issue that could be resolved via an exchange of letters or needs to go to Cabinet. Perhaps a good start would be a draft letter from [the Minister] to the Prime Minister?

4.34 On 24 May 2002, Health provided PM&C with a copy of a draft minute to the Minister for Health and Ageing recommending that the PFA not be extended and attaching a draft letter to the Prime Minister. PM&C was requested to provide any comments by close of business on 28 May 2002. A telephone record of a conversation between the BODT and PM&C on 29 May 2002 records that PM&C considered the draft minute to the Minister required strengthening in the following aspects:

> a) more information justifying why the PFA should not be extended (more detail about weakness of the PFA);
>
> b) more detail regarding the work necessary to achieve an improved PFA, if the current PFA is not extended (i.e. what is the work program to ensure a better arrangement can be put in place); and
>
> c) more detail in the letter to the PM on why the PM should agree to not exercising the extension option. This will flow from catering for the first two points above.
>
> [PM&C] asked to see another draft, noting [they] did not have enough information at present to prepare a briefing for the PM.

4.35 On 3 June 2002, Health provided PM&C with a revised draft of the minute to the Minister and letter to the Prime Minister and attaching a three-page paper summarising the strengths and weaknesses of the current PFA and the process for negotiating improved arrangements. PM&C was asked to provide Health with any feedback on the material as a matter of priority.

4.36 On 7 June 2002, officers from Health spoke with PM&C officers about the revised drafts. Health's record of the conversation states that, in summary, PM&C sought more information on the risks involved in not extending the PFA. PM&C asked for copies of the risk analysis that had been undertaken by Health, as well as copies of the letters provided by the expert legal and economic consultants (these were subsequently provided to PM&C).

4.37 The PM&C officers also asked about the option of extending the 23 June 2002 deadline to enable more time for consideration of this matter but were advised by Health officers that the PFA was clear on the deadline; that a redraft of the contract would take considerable time in terms of negotiating a variation on this matter; and it would probably not be perceived well by CSL if the Commonwealth asked for an extension on this matter at this late stage. At the request of the PM&C officers, a meeting was scheduled for 12 June 2002 to discuss the matter.

4.38 In the meantime, on 7 June 2002, a senior officer from Health spoke with the relevant senior officer in PM&C. The note for file indicates that, given the time constraints:

> [Health] must now ask [the Minister] to handle by way of exchange of letters with the PM, copied to the [Minister for Finance and Administration] and Industry Minister, as soon as possible. This would be essential to meet the 23 June deadline for communication to CSL Limited.
>
> [The PM&C officer] agreed the Minister to write ASAP, and Health to separately provide further information to PM&C on issues and risks in the meantime, to feed their advice to the PM. A meeting has been set up for this purpose.

4.39 On 11 June 2002, Health provided a minute to the Minister for Health and Ageing entitled *Advice to Government not to unilaterally extend the Plasma Fractionation Agreement beyond 30 June 2004*. The minute recommended the Minister:

- note the advice of the Department's Steering Committee not to exercise the option to unilaterally extend the PFA in its current form beyond 30 June 2004; and
- sign a letter to the Prime Minister, with copies to the Treasurer, the Minister for Finance and Administration and the Minister for Industry, Tourism and Resources, recommending the Government not exercise the option to unilaterally extend the PFA in its current form beyond 30 June 2004.

4.40 The minute advised the Minister that the Steering Committee considered that the main risk with not extending the PFA was the risk that the Department could not organise effectively to achieve optimum new supply arrangements. The Committee determined that this risk was of an acceptable level and subject to mitigation strategies. The minute noted that the Department had not undertaken any consultations with CSL on this matter but had liaised with officers of PM&C about the preferred method of progressing it through Government with the recommendation being that the Minister send a letter to the Prime Minister and other relevant Ministers.

4.41 The Minister accepted the Department's recommendations and signed a letter to the Prime Minister on 16 June 2002 that sought his agreement to the Government adopting a decision not to unilaterally extend the PFA. Copies were also provided to the Treasurer and the Ministers for Finance and Administration and Industry, Tourism and Resources. The Minister's letter advised the Prime Minister that:

> Within my Department, a thorough examination has been made of the advantages and disadvantages of exercising and not exercising the option provided in clause 2.3 [of the PFA]. The risks of each course of action have also been analysed.
>
> The analysis shows significant disadvantages with the current terms of the PFA, which will become more pronounced in the future. The risks of extension clearly outweigh the risks of negotiating a new and better agreement. Accordingly, I recommend that the Government not exercise the option to extend the PFA. I have attached a record of the Departmental Steering Committee considerations for your information.
>
> Should you agree to my recommendation, I will provide advice on future plasma fractionation arrangements, which will need to be in place before 30 June 2004, in due course.

4.42 In the meantime, Health met with officers from PM&C on 12 June 2002. At the meeting Health provided a briefing on the background to the recommendation not to extend the PFA and the reasons that the Department felt that the risks of not being able to negotiate a new agreement were of an acceptable level. Following the meeting, the PM&C officers indicated that they would be talking to Finance before completing a briefing for the Prime Minister on the Minister for Health and Ageing's letter and suggested Health should also contact Finance ahead of this to provide the necessary background and information. Health subsequently arranged a meeting with officers from Finance and Treasury on 14 June 2002.

4.43 At the meeting on 14 June 2002, officers from Finance:

- questioned the timeframe available for the decision on the option, noting that there was little time available for detailed consultation with Departments and their Ministers;
- indicated concern about the breadth of the risk analysis undertaken by Health, particularly in relation to costs; and
- indicated that the Department would want to see an economic analysis of the savings that Health envisaged would be made under a new PFA before supporting the advice not to exercise the extension option, despite the difficulties of the current PFA.

4.44 The Health officers noted at the meeting that no firm decisions had been made on any new arrangements or their duration and that the advice under discussion was about not exercising the extension option. The Health officers asked for Finance's specific questions to be emailed so that they could be addressed. This occurred later that day with a request from Finance that Health respond as soon as possible so that Finance could contribute to the PM&C briefing to the Prime Minister.

4.45 On 17 June 2002, Health responded to Finance's questions indicating that:

- estimates of the financial impacts of all elements of the proposed new arrangements, including the assumptions underpinning them could not be provided because Health was not proposing new arrangements at this point. Health advised it was just providing advice to Government on whether or not the Commonwealth should exercise its option to extend the current agreement;
- an indication of how the proposed new arrangements could achieve savings and what those savings might be could not be provided because this was not an issue for Government consideration at this time.....; and;
- it was not possible to get an extension on the 23 June 2002 deadline so that Ministers could have more time to consider the matter. Health advised Finance that this was because the date was contained in the contract and would require negotiation with CSL to amend. Health advised that this could not be undertaken in time and that, given the Department's analysis strongly militated against extending the agreement, such a course of action was not being considered by Health, even if there was time.

4.46 Late on 20 June 2002, the senior Health officer who had been liaising with PM&C emailed the then Chair of the Steering Committee advising that he had just received verbal advice from PM&C that the Minister for Health and Ageing had full authority to make the decision in relation to the PFA extension option. The Health officer noted this was the first time he had been given this advice. He noted, that in view of the urgency of the matter, he had drafted and sent to the Minister a new minute asking for her decision urgently on the PFA extension option.

4.47 On Friday 21 June 2002, the last working day before the expiry of the option on Sunday 23 June 2002, the Minister accepted the Department's recommendation to not exercise the PFA extension option. Health notified CSL in writing of the Commonwealth's decision on the same day. Subsequently, on 1 July 2002, the Minister wrote to the Prime Minister (with copies provided to the Treasurer and the Ministers for Finance and Administration and Industry, Tourism and Resources) advising him that she had decided on behalf of the

Government not to unilaterally extend the current plasma fractionation arrangements with CSL on current terms and conditions beyond 30 June 2004.

4.48 In response to ANAO's May 2003 discussion paper, Health advised that:

> The Department notes that, despite the tight timetable and some initial confusion between agencies about the Minister's authority to make the final decision, the decision was made in time and CSL advised by the due date.

Procurement contract option

4.49 A large number of Commonwealth contracts incorporate options, notably in the information technology sectors. For example, the December 1999 Health Group[55] IT contracts for the supply of IT services to the value of more than $350 million over five years to Health and the Health Insurance Commission provide options to extend for up to a further four years.[56]

4.50 An option can represent considerable value as it provides the Commonwealth with the right to buy goods and services at specific prices. The option usually arises from the procurement activity associated with a Commonwealth contract to purchase goods and services. Commonwealth procurement activity is regulated by the FMA Act, the FMA Regulations and the CPGs.

4.51 Section 44 of the FMA Act obliges Chief Executives of Commonwealth agencies to manage the affairs of their agencies in a way that promotes proper use of Commonwealth resources for which the Chief Executive is responsible. The Act defines proper use as efficient, effective and ethical use. FMA Regulation 8 requires officials performing duties in relation to the procurement of property or services to have regard to the CPGs. Figure 4.1 below sets out the nature of the CPGs issued by the Minister for Finance and Administration under FMA Regulation 7.

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[55] Comprised of Health, the Health Insurance Commission and Medibank Private Limited.

[56] See ANAO Audit Report No.14 2002–03, *Health Group IT Outsourcing Tender Process,* para 2.37, p. 67.

Figure 4.1

Commonwealth Procurement Guidelines

The Guidelines are issued by the Minister for Finance and Administration under FMA Regulation 7(1). They apply to the procurement of all property and services, and by outlining the fundamental policies and principles that underpin procurement, they articulate the expectations that exist on officials, or agents conducting procurement on behalf of the Commonwealth, in the design, conduct and management of all aspects of Government procurement.

Value for money is the core principle governing Commonwealth procurement. This core principle is underpinned by four supporting principles:

- Efficiency and Effectiveness;
- Accountability and Transparency;
- Ethics; and
- Industry Development.

These principles are also complemented by other Government policies. Fundamental to all Commonwealth procurement is that it is sufficiently transparent to allow the Government, Parliament, and the public to have the utmost confidence in the procurement process and that Chief Executives and agencies are meeting their obligations to promote the efficient, effective and ethical use of resources as stated in section 44 of the FMA Act. Officials undertaking procurement-related activity are expected to:

- act in accordance with the Guidelines;
- ensure their procurement reflects the policies and principles contained in the Guidelines;
- ensure their actions meet any additional requirements addressed in their Chief Executive Instructions (issued under FMA Regulation 6(1)); and
- recognise that they are accountable, within the framework of Ministerial accountability, to the Government, Parliament and the public. FMA Regulation 8(2*)* states an official who takes action that is not consistent with the Guidelines must make a written record of his or her reasons for doing so.

Source: Commonwealth Procurement Guidelines and Best Practice Guidelines issued by the Minister for Finance and Administration 12 February 2002

4.52 In February 2003, Health advised in response to ANAO's December 2002 issues papers that its internal legal advice was, among other things, that:

> Regulations 8 to 13[57] of the FMA Regulations, dealing with the specific decision making requirements for approving and entering into commitments to spend public money, did not apply to the decision not to extend the PFA. Had the decision been to extend the PFA, the decision would have needed to be formally given effect by appropriate delegations under these regulations (as was in fact done for the analogous decision to agree with CSL on an extension of the [Diagnostics Products Agreement]).
>
> The general obligation of the Health Chief Executive (and therefore in effect of officers under her) under section 44 of the FMA Act to make efficient, effective and ethical use of resources would of course have applied. The way this obligation was in fact met was through the establishment and work of the Steering Committee and the officers working to the Steering Committee.....
>
> The present CPGs, unlike earlier versions, deal largely with general concepts and principles rather than specifying particular detailed rules and requirements. The CPGs make the most sense when read as applying to the overall process of procurement of products under the PFA or any similar subsequent contract. The decision in relation to the extension or non-extension of the PFA is one decision in that overall process, but is not the totality of that process, and the Department's administration of that process is still continuing. The CPGs do not contain any requirements or principles which apply specifically to a decision whether or not to exercise an option under a contract.....
>
> It is also too strong a statement to say that the concept of value for money in the CPGs, together with the Chief Executive's general obligation under section 44 of the FMA Act, definitely require that the Department establish which course of action would deliver the best value for money under the overall procurement process. In the event, based on comprehensive consideration of issues over an extended period, the Steering Committee decided it did not need to know the ultimate outcome in order to recommend a position on the PFA extension.

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[57] FMA Regulation 8 requires officials to have regard to the CPGs when performing duties in relation to the procurement of property or services. Regulation 8 requires officials who take action that is not consistent with the CPGs to make a written record of their reasons for doing so. FMA Regulation 9 sets out the principles to be adhered to in approving a proposal to spend public money and requires such inquiries as are reasonable be made to satisfy the approver that the proposed expenditure is in accordance with the policies of the Commonwealth and will make efficient and effective use of public money. FMA Regulation 10 requires that the Finance Minister have given written authorisation to approvers for future spending proposals where an appropriation of money is not authorised by the provisions of an existing law or a proposed law that is before Parliament. FMA Regulation 11 provides that an official must not approve a proposal to spend public money unless authorised by a Minister or Chief Executive, or by or under an Act, to approve the proposal. FMA Regulation 12 provides that if a proposal to spend public money is not given in writing, the approver must record the terms of the approval in a document as soon as practicable after giving the approval. FMA Regulation 13 provides that person must not enter into a contract, agreement or arrangement under which public money is, or may become, payable unless a proposal to spend public money for the proposed contract, agreement or arrangement has been approved under Regulation 9 and, if necessary, in accordance with Regulation 10.

4.53 ANAO has received legal advice that the Commonwealth's decision whether or not to exercise the option to extend the operation of the PFA was a procurement-related decision and that, in this circumstance, it was a decision to which the FMA Act, the FMA Regulations and the CPGs applied.

4.54 ANAO's legal adviser noted that it might be argued that a strict interpretation of the meaning of procurement might suggest that a decision whether to extend the PFA is not a 'procurement decision' in terms of the FMA Act because it does not, by definition, relate to 'obtaining and purchasing services or supplies'. If the option is not exercised, nothing is procured under the PFA, once it expires. However, ANAO's legal adviser concluded, on the basis of a close examination of the FMA Act, FMA Regulations, CPGs and relevant parts of Health's Chief Executive Instructions, that the terms 'procurement' and 'procurement-related activity' are given a broad meaning. Accordingly, ANAO's legal adviser considered that the Commonwealth's decision regarding extension of the PFA (whether the agreement was actually extended or not) is an aspect of procurement, or at the very least, a procurement-related activity, to which the CPGs apply.

4.55 In response to ANAO's May 2003 discussion paper and the June 2003 section 19 proposed report, Health advised that:

> The legal advice received on the CPGs was provided in response to the first ANAO issues paper, well after the Department provided its advice on the PFA extension option. The Steering Committee had a strong focus on value for money issues throughout its deliberations and in the reasons for its decision and advice to Government.
>
> All applicable requirements of the FMA Act, FMA Regulations and CPGs were complied with in relation to the decision to advise government not to exercise the PFA extension option. The policy principles initially determined by the Steering Committee as the basis for its deliberations, and the information, analysis and advice actually considered by the Committee in its consideration of the exercise of the option, took account of the value for money, efficiency, effectiveness and ethics issues relevant under the FMA framework, and the relevant health policy objectives.
>
> There are no specific procedural requirements that can be drawn from the CPGs or FMA Act section 44 in relation to the decision on whether or not to exercise the option. To the extent that the decision to not exercise the option may be regarded by some as a departure from the CPGs, then the obligation in Regulation 8 to record the reasons for such a departure was met by records kept by Health of the proceedings of the Committee.

Procedural ambiguity

4.56 Given the increasing prevalence of options in major Commonwealth procurement contracts, the question as to whether or not the Commonwealth's legal and policy procurement framework applies to decisions taken on these options is an important policy issue for the Commonwealth. Finance is the Commonwealth agency with policy responsibility for both the FMA Act and establishment and support of fundamental policies and principles that underpin the Government procurement framework. This framework articulates the expectations that exist on officials in the design, conduct and management of all aspects of Commonwealth procurement. Accordingly, Finance is responsible for providing advice to its Minister on procurement policy issues; developing and supporting the CPGs; and disseminating best practice advice and tools.[58]

4.57 ANAO was advised by its legal adviser that:

> Whether or not it was a procurement activity, Health and Ageing employees were obliged to assist the Secretary to that Department to acquit her responsibility under section 44 of the FMA Act, so far as relevant, to manage the affairs of that Agency in a way that promotes efficient and effective use of Commonwealth resources for which she is responsible. These obligations would independently have required Departmental officials to take broadly the same actions as required under the procurement policies.

4.58 In light of ANAO's legal adviser's opinion that the PFA option was a procurement-related activity, that adviser gave the following advice in relation to the steps required to satisfy the requirements of procurement in this situation:

> These would involve consideration of a range of inter-related factors drawn from the FMA framework and overall arrangements (including the Commonwealth's specific requirements) for obtaining plasma products. The exercise of appropriate judgement concerning those factors, which are summarised below, would include:
>
> (a) how the FMA Act obligation on the Secretary to the Department of Health and Ageing to promote proper (that is, in this situation, efficient and effective) use of Commonwealth resources could be met;
>
> (b) what were the options for obtaining plasma products for the future;
>
> (c) all of the existing circumstances under which such products were being procured at present under the PFA, including under the existing PFA or any amended PFA or an entirely new agreement;
>
> (d) other relevant factors, such as the national interest requirements and the existence of provisions in Division 4, Part 3A of the *Commonwealth Serum Laboratories Act 1961* (the CSL Act) which enable the Commonwealth, if

[58] See Finance's website <www.finance.gov.au> Government Operations, Financial Management Framework, Procurement Framework Advice.

necessary, to ensure performance of plasma products contracts by obtaining mandatory injunctions for the treatment of risks, but which depend on a PFA being in existence;

(e) considering a strategy to achieve value for money (including efficiency and effectiveness) in accordance with the Commonwealth Procurement Guidelines;

(f) developing an appropriate risk management analysis and strategy for the treatment of risks; and

(g) compliance with other aspects of the Commonwealth Procurement Guidelines, legal requirements or Government policy requirements.

Consideration and examination of these factors would also have required:

(b) sufficient time to allow all possible options to be fully explored and taken if appropriate; and

(c) consideration of the position of CSL (including through discussions or negotiations with the company on relevant issues and options).

4.59 In response to this advice, Health advised ANAO in May 2003 that:

> Because of the general principles approach of the CPGs, it is difficult to derive any specific process requirements from them. It was open to Health to determine the particular ways in which issues raised under section 44 of the FMA Act and in the CPGs would be considered. The way these issues were, in fact, considered was through the Steering Committee process.

4.60 ANAO considers that the opportunity to exercise an option in a contract creates economic benefits and costs. Clearly, if in exercising, or not exercising, the option this involves spending more public money, the Commonwealth financial management framework applies. In light of the financial significance of options in many major Commonwealth procurement contracts, ANAO considers that it is undesirable that there be ambiguity around the procedures to be applied when deciding whether or not such an option should be exercised. In the absence of a structured governance framework which would apply to this important area of procurement activity, the risk to the Commonwealth that the decisions taken will be sub-optimal is increased and the accountabilities of officials for the processes they apply is not clear.

4.61 As noted in Health's internal legal advice of February 2003 (see paragraph 4.52), the CPGs do not currently specifically contain any guidance for agencies on options and particularly do not provide advice as to whether the CPGs apply in circumstances where agencies decide not to exercise an option. ANAO questions whether this is necessary. However, ANAO considers that there would be merit in Finance, as the responsible agency, reviewing the CPGs to determine how to specifically address this issue.

Recommendation No.1

4.62 ANAO *recommends* that the Department of Finance and Administration enhance the guidance provided in the Commonwealth Procurement Guidelines by including specific advice to agencies on the procedures to be applied to evaluating options in materially important procurement contracts.

Finance Response

4.63 **Agreed.** Finance advised ANAO that it will investigate the inclusion of the consideration of options within the whole-of-life assessment of value for money when next updating the CPGs. In the interim, Finance will consider distributing guidance in a Commonwealth Procurement Circular on the consideration of options in materially significant contracts.

4.64 Finance further advised ANAO that:

> [Finance] considers that the financial management framework sets out a clear obligation to consider the evaluation of options on a value for money basis irrespective of whether this is explicitly stated in the CPGs.
>
> Chief Executives of Commonwealth agencies subject to the FMA Act are required by section 44 of that Act to manage Commonwealth resources in an efficient, effective and ethical manner. This obligation resides with an agency Chief Executive whether or not a particular matter is referenced in the CPGs, which add to the framework provided by the FMA Act and Regulations. Finance notes that an agency's Chief Executive's Instructions, issued under the authority of the FMA Act, are designed to be available for a Chief Executive to address other elements of the framework if an agency considers there is a need for additional guidance.
>
> Furthermore, Finance notes legal advice obtained by the ANAO that the responsibilities of agency Chief Executives under section 44 of the FMA Act would be expected to involve the assessment of alternatives within the process of considering options, irrespective of whether such consideration amounts to procurement or not (see paras 4.57–4.58).
>
> Finance can confirm that Health did not seek advice from Finance regarding the potential application of procurement policy to the consideration of the extension option in the PFA at any time prior to the contact referred to in the draft Audit Report (see paras 4.42 - 4.45).
>
> Finance agrees that, given the increased incidence of options in Commonwealth contracts, there may be value in clarifying this issue in the CPGs. Finance notes that the recommendation calls for 'specific advice....on the procedures to be applied' rather than the procedures themselves. Finance considers that this is consistent with the role of the CPGs in providing high-level policy principles to

be applied in the procurement of property and services while enabling Chief Executives to determine the specific procedures that are most appropriate to their agencies' circumstances.

Canberra ACT
28 August 2003

P.J. Barrett
Auditor-General

Appendices

Appendix 1

Department of Health and Ageing's full response to the s19 proposed report

Summary

The Department's response is framed in the context of the overall policy and procurement environment in which the Plasma Fractionation Agreement (PFA) extension decision was taken. In summary, the Department considers that it:

- adopted a timely and effective approach to the PFA extension review, including consideration of value for money issues;
- fully appreciated the nature of the analysis required to underpin advice to Government;
- provided advice to the Minister based on sound analyses of the information available, in particular the findings of the comprehensive National Blood Review; and
- met its obligations under the PFA in terms of the timing of the decision and advice to CSL Ltd.

The audit was conducted at a point that meant it reflected only part of the whole policy and procurement process relating to future arrangements for the supply of plasma products. There are still policy matters relating to the future arrangements that are to be decided.

The Department's views and opinions on a number of matters raised in the report differ from those of the ANAO.

Context

The Australian blood system is large and complex.

The Commonwealth's long-standing objectives in relation to the blood system have been to ensure that Australians have access to an adequate, safe, secure and affordable supply of blood and related products.

These objectives are now enshrined in the National Blood Agreement[59] that states:

> The primary policy objectives for the Australian blood sector are:
>
> a. to provide an adequate, safe, secure and affordable supply of blood products, blood related products and blood related services in Australia; and

[59] The National Blood Agreement, an agreement between the Commonwealth and State and Territory Governments took effect from 1 July 2003.

b. to promote safe, high quality management and use of blood products, blood related products and blood related services in Australia.

The management of the blood sector to achieve these objectives goes beyond the securing of plasma derived products. It involves:

- the donors who provide source materials free of charge;
- the Commonwealth and State and Territory Governments who fund blood services;
- domestic providers, the Australian Red Cross Blood Service (ARCBS) and CSL Ltd (CSL), who provide products based on Australian sourced materials;
- international suppliers of other products;
- the Australian regulatory regime under the Therapeutic Goods Administration;
- the world market in blood products;
- the clinicians and hospitals that use blood products; and
- the patients who receive the products.

The future supply of plasma products is one important part of the broader blood and plasma product supply arrangements. Particular issues impacting future plasma product arrangements are:

- the identification of new risks relating to blood and blood product safety;
- changing technologies associated with the manufacture of plasma products;
- new products and product suppliers entering the market;
- changing conditions in the international plasma market, including mergers, actions by overseas governments and changes in the balance of supply and demand; and
- the potential for increased substitution of plasma derived products with non-plasma (recombinant or synthetic) products.

Chronology

Early in 1999 the Department identified a number of issues affecting the blood sector. These included:

- safety and quality in the production and supply systems and the need to maintain and enhance arrangements;

- the need to improve system-wide decision making processes;
- ensuring that the system was able to meet Australia's needs into the future;
- the need for strategies to increase the supply of plasma products that were in short supply; and
- the economic and productive capacity of the Australian plasma fractionation industry.

In March 1999, a briefing by the Department to the then Minister for Health and Aged Care, Dr Woolridge, canvassed a number of options for dealing with these issues, including an independent review. The briefing also noted the requirement for a decision on the PFA extension option by June 2002, and covered the issues associated with the then in-progress ANAO audit of the Department's management of plasma fractionation arrangements.

In May 1999, to address these issues, the Minister announced a comprehensive and independent review of the Australian blood banking and plasma product sector (the Blood Review). The Blood Review Committee was chaired by Sir Ninian Stephen, and also comprised other eminent Australians.

Two (2) of the five(5) terms of reference of the Blood Review related directly to the Australian plasma fractionation industry and the supply of plasma products.

Separately from the Blood Review, in April and July 2000, the Department provided submissions to the inquiry of the Joint Committee of Public Accounts and Audit (JCPAA) into the Auditor-General's Report No.24 of 1999/2000, *Commonwealth Management and Regulation of Plasma Fractionation*. These submissions, inter alia, noted the following in relation to the future management of plasma fractionation arrangements:

> The Commonwealth's policy position will be significantly assisted by the National Blood Review, which will provide a policy framework for addressing the Commonwealth's relationship with the plasma fractionation industry.
>
> (Submission dated 28 April 2000)
>
> The Department has already begun preparations for the PFA extension review.....Prior to beginning negotiations with CSL, the Department has to develop a position that takes into account, among other things, Australia's future needs for plasma products, technological and scientific choice, regulation and improving safety. As noted in the Department's April submission to the JCPAA, the Commonwealth will be significantly assisted by the National Blood Review.....
>
> (Submission dated 7 July 2000)

The Blood Review reported in March 2001, and the report was released by Government in June 2001. This report recommended, inter alia, that the

Government should enter into a second PFA with CSL rather than extend the current one. The report identified the reasons underpinning the recommendation:

> The Review supports the establishment of a new, shorter-term plasma fractionation agreement, rather than an extension of the current one. This is for several reasons. The first agreement was an historical, foundation agreement struck in 1993 at the time of the CSL sale with a specific cost structure. It was a long-term agreement covering ten and a half years. The broader environment in which blood programs and governments operate has changed over that period and further changes are likely. Other chapters have explored their implications for Australia. Service delivery and funding agreements and contractual arrangements must keep pace with and be responsive to changing circumstances and needs.[60]

Consultations over succeeding months between Commonwealth and State/Territory Governments resulted in agreement between Australian Health Ministers, in September 2001, to implement the Blood Review's recommendation to establish a National Blood Authority. This authority was established on 1 July 2003 following the passage of Commonwealth legislation and the signing of the National Blood Agreement.

In October 2001 the Department commenced planning for an internal Departmental process to follow on from the Blood Review in relation to future arrangements for plasma fractionation and other matters.

A steering committee of senior Departmental officials (the Departmental Steering Committee) first met in December 2001. The role of the Departmental Steering Committee was to provide advice to the Department on a range of matters relating to the blood sector, including plasma fractionation arrangements.

The Departmental Steering Committee met a further three times up to and including 18 April 2002, on which date it reached the recommendation that the Department would provide to the Minister concerning the PFA extension option. The Departmental Steering Committee has continued to meet regularly since then.

Throughout the review process, the Departmental Steering Committee was supported by internal and external advisers. Research and analysis was undertaken with results being used by the Departmental Steering Committee to inform its deliberations.

It should be noted that in the future, it will be the responsibility of the newly created National Blood Authority to progress work on plasma fractionation arrangements.

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[60] Review of the Australian Blood banking and Plasma Product Sector, March 2001, Section 10.3.

As part of formulating its recommendation on the PFA extension, the Departmental Steering Committee considered advice that the major risks of exercising the option to extend the PFA under the existing terms and conditions were:

- not being able to replace the now outdated objective of underpinning a successful sale of CSL with a more appropriate and relevant set of objectives;
- being unable to demonstrate the Commonwealth is achieving value for money;
- not being able to justify the non-acceptance of the recommendation of a recent, substantive and independent review of the blood banking and plasma product sector, to which the Government has already agreed in-principle (ie the Blood Review);
- precluding the opportunity to align new plasma fractionation arrangements to other sector reforms currently the subject of Government consideration and negotiation; and
- having an inflexible agreement which renders it difficult to cater for the increased use of alternatives to plasma derived products or new plasma fractionation technologies, and which may not provide enough flexibility to address the necessary relationships in the sector.[61]

On 21 June 2002, on the recommendation of the Department, the Minister took the decision not to exercise the PFA extension option. This decision was taken, and CSL was advised prior to the deadline set in the PFA for the Commonwealth to exercise the option and advise CSL.

Departmental Position on ANAO Findings

Approach to the Extension Option Review

For more than four years the Department has paid considerable attention to the blood sector issues set out in the *Context* above, including those relating to plasma fractionation. The work continued throughout the Blood Review, and afterwards under the direction of the Departmental Steering Committee.

The work undertaken assisted the Departmental Steering Committee to reach an informed conclusion in April 2002 on the PFA extension option, and enabled the Department to provide its advice to the Minister. The Departmental Steering Committee's deliberations relied significantly on the extensive work undertaken by the Blood Review.

The Department was fully aware that new plasma product supply arrangements were to be completed by 30 June 2004. However, it would not have been practical

[61] Excerpt from Agenda paper 2 for the 18 April 2002 meeting of the Steering Committee.

in that time frame to address all the environmental changes noted both in the Blood Review report and emerging since then, and all of the issues raised by the Department in its submission to the JCPAA in July 2000. This is because the last two years have seen unprecedented change in the international plasma fractionation industry, evidenced by corporate acquisitions, structural changes, new product developments and supply and price fluctuations.

For example, in July 2003 it is still not possible to know the extent to which some plasma products will be replaced with non-plasma substitutes. Such substitution, were it to occur, would have a major impact on future supply requirements for plasma derived products in Australia.

Nor would it have been prudent to commit to the details of possible future arrangements too early in such a rapidly changing environment.

Furthermore, the creation of the National Blood Authority on 1 July 2003 and new blood sector arrangements (in line with the Blood Review's recommendations) will have a significant effect on new supply arrangements. The States and Territories will be involved with the Commonwealth in setting the parameters for any major new contracts for blood products.

Accordingly, the approach adopted by the Departmental Steering Committee up to April 2002 was to complete the extension option review by that date. It aimed to complete the entire policy and procurement processes for future plasma fractionation arrangements subsequent to June 2002.

The Department decided not to enter into discussions with CSL on future plasma fractionation arrangements. As aspects of the future policy and procurement framework would be influenced by events after the June 2002 PFA extension deadline, the Department considered that it should not give a potential advantage to one supplier over other suppliers in the industry.

Overall, the Department is of the opinion that it adopted an effective and appropriate approach to the PFA extension review, with the Commonwealth meeting its contractual obligations in relation to the extension option within the required timeframe. The recommendation to the Minister resulted from a long-term, robust and well considered process.

Role of the Blood Review

The report of the Blood Review represented the most comprehensive analysis of the Australian blood and plasma products sector ever undertaken. In particular, the Blood Review Committee commissioned a major economic analysis of the PFA and the Australian plasma products sector. It was on the basis of this analysis that the Blood Review recommended that the Government not exercise the PFA extension option.

The findings of the Blood Review, and the thorough research and consultation that underpinned them, have led to major change in the way that the blood system is organised. The recommendations of the Blood Review have been regarded by all Australian Governments as timely and appropriate. This is evidenced by the fact that within around two years of the release of the Blood Review report a National Blood Agreement has been signed by all Australian Governments, and legislation passed through the Federal Parliament.

The conclusions and recommendations of the Blood Review were central to the subsequent Departmental Steering Committee's PFA extension review process.

The Departmental Steering Committee had the benefit of considering the relevant analytical papers commissioned by the Blood Review. It also commissioned and prepared other papers that further explored issues considered by the Blood Review. The Blood Review papers together with its report provide the reasoning behind the recommendation not to extend the PFA. These reasons are set out in the *Context* above.

The Departmental Steering Committee's own analysis and deliberations, including its consideration of the major risks of exercising the option to extend the PFA under existing terms and conditions, set out in the *Context* above, drew significantly on the reasoning of the Blood Review.

In particular, one of the major reasons for the Departmental Steering Committee recommending to the Department that it not extend the PFA under existing terms and conditions was '*not being able to justify the non-acceptance of the recommendation of a recent, substantive and independent review of the blood banking and plasma product sector...*'. In other words, the Departmental Steering Committee relied heavily on the Blood Review findings in reaching its conclusion.

At paragraphs 7 and 3.10 [paras 8 and 3.10 in the final report], the ANAO report notes that:

> During the Steering Committee's deliberations on the PFA extension option, the BODT advised the Committee that, in recommending the establishment of a new, shorter term agreement between the Commonwealth and CSL, the Blood Review did not consider in detail the option to extend the PFA.

This comment is in a paper provided to the Departmental Steering Committee for its meeting on 18 April 2002. At no time did the Departmental Steering Committee accept the view in the paper, or take a decision to that effect. Therefore, this comment does not represent the view of the Departmental Steering Committee. The Department is of the opinion that the ANAO has taken this comment out of context, and that the ANAO's conclusion is not supported by the evidence.

Timing of the Audit

The ANAO notes at paragraph 1.11 of the report that in October 2000 the JCPAA recommended that the ANAO undertake a timely performance audit of the Department's handling of the PFA extension review.

The ANAO commenced the audit in June 2002, immediately after the extension deadline had passed. At that time, the Department advised the ANAO (at the entry interview for the audit) that the overall policy and procurement review process for plasma products was still continuing, and that the PFA extension decision was only one step in the overall policy and procurement process which would go through until the point when a new contract was signed for plasma products.

The Department suggested that an audit of the complete process of setting in place new plasma fractionation arrangements beyond 30 June 2004 might be more appropriate, because it would enable the Department's conduct of the extension review element to be considered as part of the broader procurement process and assessed in terms of the outcome of that process.

In February 2003, the Secretary of the Department wrote to the Auditor-General expressing concerns about the timing of the audit, noting that the Department was mid-way through the process, and that there remained policy matters that were yet to be decided.

In this context, the Department noted that a 'timely' audit as requested by the JCPAA should mean 'well timed or appropriately timed and not simply rapid'. The Secretary of the Department invited the ANAO to continue the audit through the final stages of the process to the point where the new arrangements for the supply of plasma products were in place.

Five Areas for Improvement Identified by the ANAO

At paragraph 39 of the report [para 40 of the final report], the ANAO concludes that there were five key areas where improvements could have been made in Health's handling of the PFA extension review.

In the context of the Department's view expressed above, further comments on the ANAO's five conclusions are outlined below.

(i) Despite early warning by ANAO in December 1999, and coverage of this issue by the JCPAA during 2000, the Steering Committee process for this complex issue was not commenced until December 2001, some six months before the expiry of the extension option.

The Department has noted that it commenced work on the process of reviewing emerging issues in the blood sector, including those relating to plasma

fractionation, over four years ago in early 1999. In particular, the establishment of the Blood Review was a crucial first step and major component of the process.

The Department is of the view that the first meeting of the Departmental Steering Committee in December 2001 was **not** the commencement of the review process. Relevant work had been underway in the Department prior to and during the Blood Review, to ensure the Department was prepared both to support the work of the review and to consider the issues following its conclusion. The Departmental Steering Committee started its proceedings with considerable prior knowledge and drew extensively on the work of the Blood Review.

The Department therefore does not agree with the conclusion of the ANAO.

(ii) There was a lack of appreciation by the Department of the nature of the analysis required to underpin adequate advice to the government on whether or not to exercise the option.

As noted in the above discussion, the Department is of the opinion that it fully appreciated the nature of the analysis required to underpin adequate advice to government.

The Department considers that the basis for the ANAO's conclusion relates to a perception that the Department did not fully appreciate the future financial value of the two-tier pricing arrangement.

The Department's view is that the most important analysis required in relation to the two-tier pricing arrangements was whether the benefits would continue if the extension option were taken up. Having undertaken this analysis, the Department concluded that, based on its assessment of future product requirements, the arrangements might be of limited financial value.

The Departmental Steering Committee identified that a major challenge for the future was to deal with the increasing demand for substitutes for some plasma products, and with a potential over-supply of some products. In particular, there was a likelihood that beyond June 2004 synthetic products would increasingly replace plasma-driven coagulation products. Under the two-tier pricing arrangements any fall in demand increases average prices and if demand fell below the minimum volume, the current PFA provides for the possibility of compensating price adjustment.

The Departmental Steering Committee concluded that the benefits of the two-tier pricing arrangements would be more than offset by these two countervailing factors. This was the crucial analysis required at the time.

The Department's opinion on the matter therefore differs from that of the ANAO.

(iii) The Steering Committee determined that it did not have to establish the best value for money approach for the future supply of plasma products before making its recommendation as to whether or not to exercise the extension option.

The Department had a strong focus on value for money issues. Nowhere in the minutes of its meetings did the Departmental Steering Committee determine that it did not have to establish a best value for money approach. As noted above, the Departmental Steering Committee considered the value for money issue as a major risk of extending the PFA.

The Departmental Steering Committee identified several weaknesses in the current PFA that would reduce value for money were it to be extended. It decided that the weaknesses could be eliminated and further advantages obtained by developing new supply arrangements.

The Department considers that the ANAO's conclusions about the Department's approach to value for money issues (paragraphs 19 to 26 [paras 20 to 27 of the final report]) appear to relate principally to two findings:

1. that the legal advice provided to the Departmental Steering Committee on the revenue maintenance provisions overstated the financial impact of reduced demand for products; and
2. that the Departmental Steering Committee did not quantify the future benefits of the two-tier pricing arrangements.

In relation to the first point, and in response to the audit, the Department obtained advice from the Chief General Counsel at the Australian Government Solicitor (AGS) that substantially confirmed the legal advice received by the Departmental Steering Committee.

The Department considers that the AGS advice supports the basis for the Departmental Steering Committee's consideration of the value for money issues.

In relation to the second point, the Department has already discussed under (ii) above its conclusion that the financial arrangements (including the two-tier pricing arrangements) in the current PFA, struck nine and a half years ago, and in the context of the sale of CSL, were unlikely to secure the best value for money for the Commonwealth.

(iv) In reaching its conclusions about extending the PFA at no time did the Department consult with CSL.

The Department has addressed this matter in its discussion above on the approach to the PFA extension review. It has been noted that as aspects of the future policy and procurement framework would be influenced by events after

the June 2002 PFA extension deadline, the Department considered that it should not give a potential advantage to one supplier over other potential suppliers in the industry. Accordingly, the Department decided not to consult with CSL during the extension option review stage.

The Department's opinion differs from the ANAO's conclusion on this matter.

(v) The process to advise Government of Health's recommendation not to exercise the option was undertaken very late, restricting the opportunity for adequate consultation with senior Ministers and detailed consideration of the Department's advice.

The extension decision was taken within the time required in the PFA and the process to advise the Government met the requirements placed on the Department for consultation.

The Department notes that, despite the initial need to clarify between agencies that the Minister had the authority to make the final decision, it was determined that the decision on the extension was one for the Minister alone. Therefore, the process was one of advice, not a requirement to obtain agreement.

Accordingly, the Department does not agree with the ANAO's conclusion on this matter.

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