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Performance Audit

Commonwealth Management and Regulation of Plasma Fractionation

Department of Health and Aged Care

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
22 December 1999

Dear Madam President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Department of Health and Aged Care in accordance with the authority contained in the *Auditor-General Act 1997*. I present this report of this audit, and the accompanying brochure, to the Parliament. The report is titled *Commonwealth Management and Regulation of Plasma Fractionation.*

Following its tabling in Parliament, 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

AIDS	Acquired Immune Deficiency Syndrome
ARC	Australian Red Cross
ARCBS	Australian Red Cross Blood Service
ANAO	Australian National Audit Office
AQIS	Australian Quarantine Inspection Service
ARTG	Australian Register of Therapeutic Goods
CJD	Creuzfeld Jakob Disease
CSL	CSL Limited
DHAC	Department of Health and Aged Care
DHSH	Former Department of Human Services and Health
DPA	Diagnostic Products Agreement
DOF	(Former) Department of Finance
DOFA	Department of Finance and Administration
EU	European Union
GMP	Code of Good Manufacturing Practice
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
ISTB	International Society of Blood Transfusion
JCPAA	Joint Committee of Public Accounts and Audit
MPI	Manufacturing Price Index
NSW	New South Wales
PFA	Plasma Fractionation Agreement
SOP	Standard Operating Procedures
TGA	Therapeutic Goods Administration

Summary and Recommendations

Summary

Background

1. The Commonwealth Government, through the Department of Health and Aged Care (DHAC), funds the domestic production of plasma derived products which are provided to the Australian community free of charge. The Department is also responsible for the regulation of the industry. The *Therapeutic Goods Administration Act 1989* provides the legislative authority for this regulation which is undertaken by the Therapeutic Goods Administration (TGA) within DHAC.

2. Plasma collected by the Australian Red Cross Blood Service from Australian volunteer donors is supplied to CSL Limited (CSL), to be manufactured into plasma derived products. The manufactured products are then either returned to ARCBS for distribution throughout Australia to hospitals and medical practitioners, free of charge, or provided directly to authorised individuals and organisations.

3. In May 1994, the Commonwealth sold CSL by means of a 100 per cent public float. On 23 December 1993, ahead of the sale, CSL and the Commonwealth signed the Plasma Fractionation Agreement (PFA). The PFA is the contract governing the supply and funding of plasma-derived products produced by CSL for distribution by ARCBS.[1] The contract covers an initial term commencing on 1 January 1994 and ending on 30 June 2004 but may be extended a further five years or longer at the Commonwealth's discretion.

4. The Broadmeadows plant involves significant excess capacity above that required to process domestic plasma supplies. Accordingly, CSL also processes at the Broadmeadows plant plasma from overseas sources. The finished plasma products are then exported.

5. In 1998–99, the Commonwealth made payments under the PFA to CSL for plasma-derived products amounting to $109.5 million.[2] Estimated Commonwealth expenditure under the initial 10½ year term of the PFA

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[1] An associated contract, the Diagnostic Products Agreement (DPA) was also signed on 23 December 1993. Under this contract, CSL produces diagnostic products from blood obtained from donations by individuals collected within Australia. The DPA commenced on 1 January 1994 and continues in force until 30 June 2001, extendable for up to a further three years at the discretion of the Commonwealth. In 1998–99, payments to CSL for products produced under the DPA amounted to $5.7 million.

[2] Total expenditure on Commonwealth blood products funding in 1997–98 was $114.7 million. This included payments totalling $101.7 million for domestic plasma products fractionated by CSL, $5.8 million for diagnostic blood products produced by CSL, $4.5 million for Recombinant Factor VIII and $2.7 million for other imported blood products.

is expected to total some $1 billion in nominal dollars. In this respect, and in light of the critical importance to the Australian community of plasma-derived products, DHAC's management of the PFA and regulation of CSL's manufacture of these products is seen as important area for ANAO performance audit coverage.

Audit approach

6. The development and initial implementation of the PFA were examined in Audit Report No.14 1995–96, *The Sale of CSL—Commonwealth Blood Product Funding and Regulation*, which was tabled in Parliament in November 1995. The 1995–96 audit report made 15 recommendations. Four of the recommendations related to ongoing blood product funding and regulation issues and these recommendations have been followed up in the context of this audit.

7. This audit represents the first occasion on which ANAO has reviewed Commonwealth management of a material long term contract let in association with a significant asset sale. ANAO's audit objectives were to:

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

Audit conclusions

8. ANAO considers that there is significant scope for improvement in DHAC's contract management practices in relation to the PFA. Marked deficiencies were found in the Department's payment control system for $400 million in Commonwealth payments under the PFA; its planning and conduct of commercial negotiations with CSL over price adjustments; and its management of the Commonwealth's exposures under product liability indemnities provided to the company for AIDS and Hepatitis.

9. ANAO identified that TGA's regulation of plasma fractionation could be improved by giving greater emphasis to ensuring timely resolution of significant non conformities with the regulatory requirements under the *Therapeutic Goods Administration Act 1989.* ANAO commends the recent improvements to TGA's procedures and practices for auditing compliance with the Code of Good Manufacturing Practice aimed at ensuring that significant nonconformities identified during audits do not remain unresolved for extended periods of time.

10. TGA advised the ANAO in September 1999 that it has incorporated the need for regular unannounced audits of CSL in its audit scheduling program. ANAO supports this initiative to improve TGA's strategic planning of its auditing of CSL's compliance with regulatory arrangements. The introduction from 7 December 1998 of formal legal prerequisites for the processing of foreign plasma at the facility, which also manufactures Australia's domestic plasma products supply, addresses an issue raised in the ANAO's 1995–96 Audit Report referred to earlier.

11. ANAO made three recommendations for improving DHAC's contract management of the PFA and implementation of plasma fractionation regulatory arrangements.

Contract management

12. There has been an absence of adequate financial controls over payments made by DHAC under the PFA. Between 1 January 1994 and April 1999, DHAC paid out more than $400 million of Commonwealth funds under the PFA without a formal process in place to confirm that the products it was invoiced for had actually been received by the designated recipients. DHAC advised ANAO in November 1999 that it had engaged a consultant in September 1999 to undertake a scoping exercise on the invoice reconciliation program. On the basis of that scoping study, the consultant advised DHAC that

> *there was a high level of matching between the products received by ARCBS and those invoiced by CSL and while a more comprehensive and formalised process was required, there did not appear to be a high risk of mis-payment or fraud.*

13. ANAO indicated in its 1995–96 audit report on the sale of CSL that DHAC did not have in place an internal control system which could reconcile invoices provided by CSL with recipients' receipt of products. Accordingly, ANAO recommended that the Department review its management information system for monitoring payment for products supplied under the PFA. DHAC advised ANAO at the time that it was currently addressing the matter. In April 1996, DHAC's Audit and Fraud Control Branch made a similar finding and recommendation.

14. Notwithstanding the recommendations of both the previous ANAO audit report and the Department's Audit and Fraud Control Branch report, and that the issue was again raised by ANAO in the context of the current audit in October 1998, no appreciable progress in developing and implementing appropriate reconciliation strategies was achieved by the Department prior to April 1999. The Department advised ANAO that it has now moved to develop and implement relevant reconciliation processes.

Initial Plasma Fractionation Agreement review

15. The PFA provided for an independent expert to review CSL's costs in 1995; provide evidence of the reasonableness of those costs; and, if necessary, adjust the price schedule. The expert's decision was to be binding on both the Department and CSL. However, 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 the Department 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.

16. DHAC did not take action to initiate the Initial Review, which had to be completed by 30 April 1996, until late January 1996. As a consequence, the consultants did not commence work until March 1996. In this circumstance, the time available to address the extremely complex issues that arose in the course of the review was severely constrained. The Department also failed to execute a written contract with the consultants who undertook the Initial Review.

17. The Department advised ANAO that, in late 1995 and early 1996, the area of DHAC responsible for the management of the PFA lacked access to any relevant corporate memory as no departmental officers who had been involved in the development of the CSL contracts were employed in the relevant Section or Branch. The resources allocated to the Department's management of the PFA were insufficient given the large range of other responsibilities also allocated to the relevant managers. As a consequence, the complexity of the PFA and the Initial Review were not appreciated by the responsible departmental managers and appropriate planning for the Initial Review was not undertaken. DHAC advised ANAO in August 1999 that it was moving to create a new Section that will be responsible for the management of the Commonwealth's contracts with CSL and other blood programs.

18. ANAO's legal advice is that the review process actually undertaken for the 1996 Initial Review 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 the Department's agreement, was in the nature of a mediation.

19. The review consultants identified that CSL had calculated the depreciation amount to apply as a result of the 1996 Initial Review on the basis of the full historical cost of all assets owned at 31 December 1995 ($246.2 million). The Department accepted CSL's approach, without seeking its own appropriate expert legal and accounting advice, to value the assets at their full historical cost as opposed to their written down

value. The outcome of this was that some $35 million which CSL had received in respect of depreciation on its assets in 1994 and 1995 was added back into the total asset base value. Under Schedule B of the PFA, half of this amount, some $17 million, was then taken into account in deriving the prices to be paid to CSL from 1 July 1996 and will be effectively double counted in the derivation of product prices over the term of the contract, notwithstanding any other factors which may have been taken into account in determining the prices.

20. In Calendar Year 1995, CSL's labour costs were $16.7 million, which was $5.7 million or some 52 per cent more than the forecast of almost $11 million. Staff numbers were 117 people and 58.5 per cent more than forecast. The Department accepted all of CSL's arguments for the increases in labour costs as reasonable and agreed that the cost structure on which prices were based be adjusted accordingly. DHAC also agreed to the removal of chromatographic gels from the asset base and the inclusion of an amount of some $876 000 for these gels into CSL's 1995 Calendar Year cost structure. No replacement cost for chromatographic gels was actually incurred by CSL in 1995 but CSL has advised ANAO that, since July 1996, average expenditure on chromatographic gels has been in the order of $1 million per annum.

Indemnities and insurance

21. Until ANAO requested it ask CSL for them, DHAC did not have in its records copies of insurance policies obtained by CSL in respect of risks for which it is indemnified by the Commonwealth. This was so, notwithstanding that in the case of CSL's HIV/AIDS insurance policy, the Commonwealth meets 90 per cent of the premium cost. In light of the indemnities granted by the Commonwealth to CSL, it is important for the appropriate protection of the Commonwealth's interests that DHAC ensure, as part of good risk management, it vets any insurance contract entered into by CSL in relation to those risks for which the Commonwealth has previously accepted liability.

22. In October 1998, ANAO requested information on any payments made by the Commonwealth in respect of the pre-sale and post-sale Commonwealth product liability indemnities granted to CSL. The Department advised ANAO that no claims had been made in respect of persons becoming HIV-positive[3] or contracting an AIDS-related condition or Hepatitis (the two conditions for which post-sale Commonwealth indemnity had been provided) through the use of a CSL plasma product manufactured from Australian blood or plasma since the commencement of the PFA.

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[3] That is test positive for the Human Immunodeficiency Virus, the retrovirus responsible for AIDS.

23. The Department did not respond to ANAO's request for information on the number and value of claims per year against the pre-sale indemnities until February 1999. DHAC advised ANAO that it did know the total number and value of settlements but that it took time to determine the number and value of claims settled per year. Payments totalling some $19.6 million were paid out by the Commonwealth in settlement of claims from people who contracted HIV/AIDS prior to the introduction of effective screening tests for the virus in the mid 1980's.

Product safety regulation

24. TGA's May 1998 audit of CSL's Bioplasma Division's compliance with the code of Good Manufacturing Practice (GMP) was not finalised, and the company's compliance with the code of GMP rated acceptable, until January 1999, some eight months after the audit was carried out. TGA's audit database was not updated until mid April 1999 to reflect the decision to finalise the audit.

25. TGA issued Certificates of GMP Compliance to CSL in February 1999 which relied on the May 1998 audit as evidence of CSL's compliance with the code of GMP notwithstanding that the audit was not recorded as finalised in its audit database. TGA has now amended its internal procedure for issuing Certificates of GMP Compliance to make it clear that these certificates must not be issued unless the audit referred to on the certificate has been recorded as finalised in the database.

26. TGA advised ANAO in September 1999 that it has reviewed its procedures and practices for auditing compliance with the Code of Good Manufacturing practice and taken remedial action to ensure significant nonconformities identified during audits do not remain unresolved for extended periods of time.

27. An incident occurred in October/November 1998 with the New South Wales ARCBS involving a failed batch of a screening kit for Hepatitis C Virus (HCV). As a result, inadequately screened plasma was sent to CSL. Retesting of all of the donations affected by the test kit failure was commissioned by ARCBS. The final outcome was that no donations involved in the test kit failure tested positive for HCV.

28. While ARCBS advised CSL of the matter on 5 November 1998, TGA was not notified by NSW ACRBS until 11 November 1998. In July 1999, TGA provided ANAO with a chronology of events for the incident which indicated that CSL, as sponsor of the relevant therapeutic good, notified TGA of the problem by telephone on 13 November 1998 followed by formal notification to TGA by facsimile on 17 November 1998.

Regulation of foreign sourced plasma

29. ANAO recommended in Audit Report No.14 1995–96, that the Department review the system for regulating foreign sourced blood and plasma processing in Australia and advise Ministers on any legislative changes required. Consequently, the Department convened a meeting in February 1996 of interested parties. The meeting concluded there was no need to recommend to Ministers that the legislation be amended, provided that CSL and the overseas plasma collection agencies providing plasma to CSL for fractionation agreed to implement contracts consistent with the European Committee for Proprietary Medicinal Products (CPMP) guideline III/5272/94 and TGA adopted procedures for ensuring compliance with these requirements.

30. In September 1996, TGA and CSL reached an agreement whereby the company would provide TGA with Plasma Master Files (as per CPMP Guideline III/5272/94) for any plasma obtained from overseas. In October 1998, TGA detected that CSL had breached this agreement by importing and processing plasma from at least one US source without TGA's knowledge and without submitting, in advance, the plasma master file for this source to TGA.

31. As a consequence, on 24 November 1998, TGA undertook its first ever unannounced audit of CSL's Broadmeadows facility during which confirmation of breaches of the 1996 agreement was obtained. During this audit, TGA also reaffirmed that it was satisfied that CSL's segregation and cleaning procedures are satisfactory and should ensure that there is minimal risk of contamination of Australian product.

32. Following identification of CSL's breaches of their 1996 agreement, TGA moved quickly to amend the *Therapeutic Goods (Manufacturing Principles)*. As a result, from 7 December 1998 any Australian manufacturer of blood products for domestic consumption is required to submit plasma master files for any foreign source. Also, the former may not process any plasma from such a foreign source until advised by the Secretary or his delegate that, based upon the plasma master files and having taken into account the plant's processes, the plasma from the foreign source will not contaminate the Australian product with any blood borne pathogens.

33. TGA advised ANAO in May 1999 that CSL had submitted plasma master files for each of the foreign sources of plasma processed at the Broadmeadows plant. However, between 7 December 1998 and 10 June 1999, with TGA's concurrence, CSL continued to process plasma from four foreign countries without having been advised in accordance with the revised requirements of the Manufacturing Principles. On 10 June

1999, the Secretary's delegate wrote to CSL providing the requisite advice for plasma from these four countries.

34. In May 1999, the Minister for Health and Aged Care commissioned an independent inquiry into the incident of the processing of foreign plasma at CSL's Broadmeadows plant without TGA's regulatory requirements having been met. The independent expert's report advised that CSL acknowledged it had failed to meet the regulatory requirements of TGA for foreign plasma but that the standard operating procedures in place at CSL since its commissioning ensured that there was no risk to viral safety arising as a result of processing foreign plasma.

35. TGA advised ANAO in September 1999 that it has incorporated the need for regular unannounced audits of CSL in its audit scheduling program. ANAO welcomes this initiative to improve TGA's strategic planning of its auditing of CSL's compliance with regulatory arrangements.

36. In relation to the breaches of the 1996 agreement between CSL and TGA on foreign sourced plasma, and the incident involving the failure of a batch of HCV test kits used by the NSW ARCBS, TGA advised ANAO that

> *it considers that these events have not had any material adverse impact on the Australian plasma products system.*

Recommendations

Set out below are the ANAO's recommendations with Department of Health and Aged Care's abbreviated responses. The Department of Health and Aged Care has provided a more detailed response to Recommendation No.1 which is shown in the body of the report as are the ANAO's findings.

Recommendation No.1 Para. 2.42

ANAO *recommends* that the Department of Health and Aged Care enhance its accountability for performance by improving its monitoring of compliance with Departmental audit follow-up procedures to ensure all relevant external and internal audit recommendations are implemented in a timely fashion.

Department of Health and Aged Care: Agreed.

Recommendation No.2 Para. 3.17

ANAO *recommends* that the Department of Health and Aged Care:

(a) for future engagements of consultants, ensure that a formal written contract is signed prior to work commencing and that a copy is retained by the Department;

(b) commence early planning for the expiry of the initial term of the PFA contract to ensure that the Commonwealth can advise CSL Limited of its preferred position by May 2002; and

(c) ensure that, in considering options for future supply of plasma products following the expiry of initial term of the PFA, the Department seeks appropriate expert legal, financial and product advice before entering into any contract negotiations.

Department of Health and Aged Care: Agreed.

Recommendation No.3 Para. 4.40

ANAO *recommends* that the Therapeutic Goods Administration clarify the reporting arrangements for incidents, such as test kit failures, to ensure that the Australian Red Cross Blood Service simultaneously notifies them to both CSL, as product sponsor, and the Therapeutic Goods Administration, as product safety regulator.

Department of Health Aged Care: Agreed.

Audit Findings and Conclusions

1. Introduction

This chapter outlines the background to the Plasma Fractionation Agreement, audit approach, overall audit conclusions and report outline.

Background

1.1 Human blood and blood products, including plasma-derived products[4], are critical healthcare products for which there is continuing and growing demand. The Commonwealth Government, through the Department of Health and Aged Care (DHAC)[5], funds the domestic production of plasma derived products by CSL Limited (CSL). In 1998–99 the funding amounted to $109.5 million. These processed plasma products are consequently provided to the Australian community free of charge.

1.2 The Department is also responsible for the regulation of the therapeutic goods industry, including the manufacture of plasma derived products. The *Therapeutic Goods Act 1989* provides the legislative authority for this regulation which is undertaken by the Therapeutic Goods Administration (TGA) within DHAC.

1.3 In Australia almost all blood to be used for therapeutic purposes is collected by the Australian Red Cross Blood Service (ARCBS) from voluntary donors.[6] The operations of the ARCBS are funded by the Commonwealth and State and Territory Governments with the Commonwealth providing 40 per cent of the funding and the relevant State or Territory Government providing the remaining 60 per cent. Plasma derived from blood collected by ARCBS from Australian donors is supplied to CSL to be manufactured into plasma derived products. CSL is the exclusive manufacturer in Australia of products derived from human plasma. The manufactured products are then either returned to ARCBS for distribution throughout Australia to hospitals and medical practitioners free of charge, or provided directly to authorised individuals and organizations.

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4 The major manufacture 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 constituents (or fractions) is achieved.

5 The Department has had various names in the past. The current name and acronym of the Department (that is the Department of Health and Aged Care (DHAC)) will be used in this report.

6 Some blood is collected in hospitals and private pathology laboratories for purposes such as autologous donations.

1.4 There are two contracts between the Commonwealth and CSL which govern the production by CSL of products derived from Australian blood for domestic consumption—the Diagnostic Products Agreement (DPA) and the Plasma Fractionation Agreement (PFA). The DPA concerns supply and funding of a range of diagnostic products produced by CSL from human blood, while the PFA relates to the supply and funding of plasma-derived products for human therapeutic use by the Australian community.

1.5 CSL was a wholly owned Commonwealth company until May 1994 when 100 per cent of the company's stock was floated on the Australian Stock Exchange.[7] Ahead of the float, on 23 December 1993, CSL and the Commonwealth signed the DPA and the PFA. The Commonwealth entered the contracts to ensure the continuation of the supply of these products after the sale of CSL.

1.6 Both the DPA and the PFA commenced on 1 January 1994. The DPA continues in force until 30 June 2001 extendable up to a further three years at the discretion of the Commonwealth.[8] The PFA covers an initial term commencing on 1 January 1994 and ending on 30 June 2004 but may be extended a further five years or longer at the Commonwealth's discretion.[9] The PFA is the more material of the two contracts involving Commonwealth expenditure of $109.5 million in 1998–99 as compared to $5.7 million for products supplied under the DPA.

1.7 Estimated Commonwealth expenditure under the initial 10½ year term of the PFA is expected to total some $1 billion in nominal dollars. In this circumstance, and in light of the critical importance to the Australian community of plasma-derived products, DHAC's management of the PFA and regulation of the manufacture of these products is seen as important area for ANAO audit coverage.

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7 The final issue price for CSL shares in the May 1994 float was set at $2.30 generating gross sale proceeds of some $299 million. The price of CSL shares as at close of trading on 25 November 1999 was $21.45.

8 If the Commonwealth wished to extend the DPA for a further period of up to three years commencing upon 1 July 2001, then the Commonwealth was obliged to notify CSL in writing of this by 30 June 1999.

9 The PFA provides that, no later than six months after the eighth anniversary of the Execution Date (that is 23 May 2002) the Commonwealth will decide whether the PFA will be extended to 30 June 2009, or such later date as the Commonwealth decides.

Plasma Fractionation Agreement provisions

1.8 Under the PFA, the Bioplasma Division of CSL processes the plasma sent to it by ARCBS into a specified range of plasma-derived products agreed between DHAC and CSL. The products comprise three broad groups, pro-coagulants, immunoglobulins and plasma volume expanders.[10]

1.9 CSL's plasma fractionation facility at Broadmeadows in Victoria commenced operations in 1994. Prior to this, plasma fractionation had occurred at CSL's Parkville facility. Payments for products produced by CSL are based on a fixed price for each unit of production. The specified range of products can be added to or varied by agreement between the parties. The contract provides that, if the effect of any such alteration on the prices of the remaining products is unable to be agreed by the parties, an expert will be required to arbitrate. The contract also provides for the incorporation of new products into the pricing framework.

1.10 Due to the national interest in ensuring continuity of supply of these critical healthcare products to the Australian community, 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 contract if CSL fails without just cause or excuse to manufacture product or otherwise breaches the contract.[11] The Act also includes provisions preventing CSL from encumbering the Broadmeadow's facility without Commonwealth consent and restricts CSL's ability to dispose of plant and equipment at the facility without such consent.

1.11 The PFA reflects these statutory provisions in the range of specified acts of default which permit termination of the contract at the option of the Commonwealth. The contract is also terminable at the option of CSL in the case of certain specified acts of default by the Commonwealth.

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[10] Pro-coagulants are primarily used to treat Australia's haemophiliac community. Haemophilia is a blood disorder leading to uncontrolled bleeding, in severe cases, due to clotting deficiencies. Immunoglobulins are used to treat people whose immune system is unable to synthesise necessary antibodies against microbiological infection. Albumin (plasma volume expanders) is used to treat burns victims and other patients losing large amounts of blood in trauma situations.

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

Figure 1.1

CSL's perspective on the environment at the time the PFA was negotiated

In the December quarter of 1993 when the PFA was negotiated, CSL was heavily committed to the management of the construction of a world class plasma fractionation plant in Broadmeadows, involving some 450 contractors and subcontractors. The plant commenced partial operation in January 1994 and attained full operation in July 1995 after an extensive commissioning and validation phase of some two years. We were also involved in a major training program for existing and new staff to take up positions at the new plant.

In addition to the above we were preparing for privatisation in May 1994 with the added responsibility of due diligence and the necessity to have a commercial plasma fractionation agreement with the Commonwealth which would survive this process and satisfy our future shareholders.

While we had historical results for our plasma operations at Parkville, we had no actual figures for the production of plasma products at the new Broadmeadows plant at the time of the negotiation. As you are aware the Broadmeadows plant is one of the most advanced and modern plasma plants in the world. We retained [an adviser] to assist us in building a cost model of the plant's future operations.

The Department was also demanding. They required a 10 to 15 year commercial agreement which locked in prices for this period, subject to one review in 1996 which was called the Initial Review. They were also required to set prices within: Pharmaceutical Benefit guidelines and practice limiting plasma product prices to a maximum of 85% of European prices; and Department of Finance guidelines issued to Government Business Enterprises, regarding Return on Funds Employed.

The PFA was negotiated in this environment and in CSL's view, it took a considerable business risk in committing itself to such an agreement. During the negotiation process, an understanding on future price adjustments was reached with the Department, and as far as possible this was included in Schedule B of the PFA. As the PFA was necessarily complex, and had several unique issues to be covered, it was necessary to include a number of special clauses in Schedule B to cover such items as depreciation, international/domestic production and specific cost allocations.

Source: CSL Limited, 24 November 1999.

Previous ANAO audit coverage

1.12 The development and initial implementation of the PFA was examined in Audit Report No.14 1995–96, *The Sale of CSL—Commonwealth Blood Product Funding and Regulation*, which was tabled in Parliament in November 1995.[12] The 1995–96 audit report made 15 recommendations. Four of the recommendations (see Figure 1.2) related to ongoing blood product funding and regulation issue. These recommendations have been followed up in the context of this audit.

[12] ANAO's objectives in auditing the sale of CSL were to review the extent to which the then Government's sale objectives were achieved; to review the management of the sale process; and to assess ongoing Commonwealth exposures and responsibilities.

1.13 Key risks arising from the PFA identified by the 1995–96 audit report related to the ongoing financial management of the contract and the Commonwealth indemnity granted to CSL under the PFA for certain post-sale production risks. To facilitate the sale of CSL and to ensure CSL's agreement to entering into a long term agreement with the Commonwealth to fractionate national plasma product supplies, the Commonwealth agreed to the inclusion in the PFA of an indemnity for CSL for claims by persons who become HIV-positive[13] or who contract an AIDS-related condition or hepatitis through the use of a CSL plasma product manufactured from Australian blood or plasma during the term of the PFA.[14] At the time the PFA was signed, in December 1993, CSL did not have insurance cover for such claims. In addition, various pre-sale indemnities which had been provided to CSL by the Commonwealth were formalised and extended in an Indemnity Agreement also signed in December 1993.

1.14 The management of indemnities across Commonwealth agencies was examined in ANAO audit reports in 1996 and 1998.[15] The indemnities granted to CSL were also considered in this context. On 26 July 1996, the then Joint Committee of Public Accounts (JCPA)[16], as part of its review of 1995–96 Auditor-General reports, held public hearings on Audit Report No.14 1995–96. In February 1997, JCPA Report 349 *Review of Auditor-General's Reports 1995–96* was released. The Committee's recommendations focussed on improving the processes for future Commonwealth contracts and indemnities.

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[13] That is test positive for the Human Immunodeficiency Virus, the retrovirus responsible for AIDS.

[14] A similar indemnity is included in the DPA.

[15] Audit Report No.6 1996–97, *Commonwealth Guarantees, Indemnities and Letters of Comfort* and Audit Report No.47 1997–98, *Management of Commonwealth Guarantees, Indemnities and Letters of Comfort*.

[16] Upon commencement of the *Auditor-General Act 1997* on 1 January 1998, the Joint Committee of Public Accounts became the Joint Committee of Public Accounts and Audit.

Figure 1.2

Recommendations concerning blood product funding and regulation and DHAC responses from ANAO Audit Report No.14 1995–96

ANAO Recommendations	*DHAC Responses*
ANAO recommends that the Department of Health and Aged Care consider strategies for establishing a more market-oriented demand framework for blood plasma products, having regard to its existing contractual obligations.[1]	**Agree in principle** with the objective of making supply of blood and blood products more responsive to demand. However, the Department notes the considerable difficulties in adopting a conventional market framework for a product where the raw material (ie. blood donations) is provided free of charge by the Australian public and where there is a single national producer.
ANAO recommends that the Department of Health and Aged Care review its management information system for monitoring payment for blood products.[2]	**Agree.** This is currently being addressed by the Department.
ANAO recommends that TGA seriously consider conducting a formal evaluation of the merits of adopting a specialised Code of Good Manufacturing Practice for fractionation of plasma products as part of its overall risk strategy assessment.[3]	**Disagree** with the recommended formal evaluation but note that the Department has already sought advice on the suggestion from the Secretariat of the Pharmaceutical Inspection Convention, which is the pre- eminent international body on GMP. The Department's action on this will depend on the advice from this and other expert sources.
ANAO recommends that the Department of Health and Aged Care should review the current system for regulating foreign sourced plasma processing in Australia and advise Ministers on any legislative changes required.[4]	**Agree**

Notes:

1 Recommendation No.11, Para 4.71, ANAO Audit Report No.14 1995–96

2 Recommendation No.12, Para 4.76, Ibid

3 Recommendation No.14, Para 5.14, Ibid

4 Recommendation No.15, Para 5.35, Ibid

Source: ANAO Audit Report No.14 1995–96 *The Sale of CSL —Commonwealth Blood Product Funding and Regulation.*

Audit approach

1.15 This audit represents the first occasion on which ANAO has reviewed Commonwealth management of a material long term contract let in association with a significant asset sale. In asset sales including long term contracts, the effectiveness of risk identification and assessment during the sales process, and agencies' management of these risks following the sale, is particularly important as the Commonwealth's ongoing exposure is much greater than in sales where valuable long term contracts are not an integral element of the sales process. In the case of

CSL and the PFA, the Commonwealth as well as being the customer is also the regulator of the industry. In this circumstance, the Commonwealth's ongoing exposures also include those relating to the effective regulation of CSL's plasma products manufacturing activities.

1.16 ANAO's audit objectives were to:

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

1.17 ANAO conducted opening interviews with what is now the Acute and Coordinated Care Branch in the Health Services Division of DHAC in August 1998 and with the TGA in September 1998. Initial fieldwork was undertaken in both divisions following the entry interviews and this work was largely concluded by November 1998. Additional fieldwork was undertaken in April and August 1999.

1.18 Meetings were held with the Acute and Coordinated Care Branch in October and December 1998 and with TGA in November 1998. ANAO requested information from both the Acute and Coordinated Care Branch and TGA that was not received until February 1999. Following analysis of this information and other data collected by ANAO, further information on a range of matters was requested from the Department with detailed responses being provided in mid July 1999. In the meantime, ANAO had met with the Acute and Coordinated Care Branch in February and April 1999 and a further meeting was held in August 1999 following receipt of the detailed responses from the Department. ANAO also met with TGA in May 1999.

1.19 DHAC advised ANAO that it had some difficulty in responding to a number of ANAO's requests because of the complexity of unravelling the issues well after events, such as the 1996 review of CSL's cost structure and prices under the PFA. The complexity of issues involved in the audit, together with the difficulties encountered by the Department in providing information and advice on these issues, required ANAO to budget additional time and resources to complete the audit.

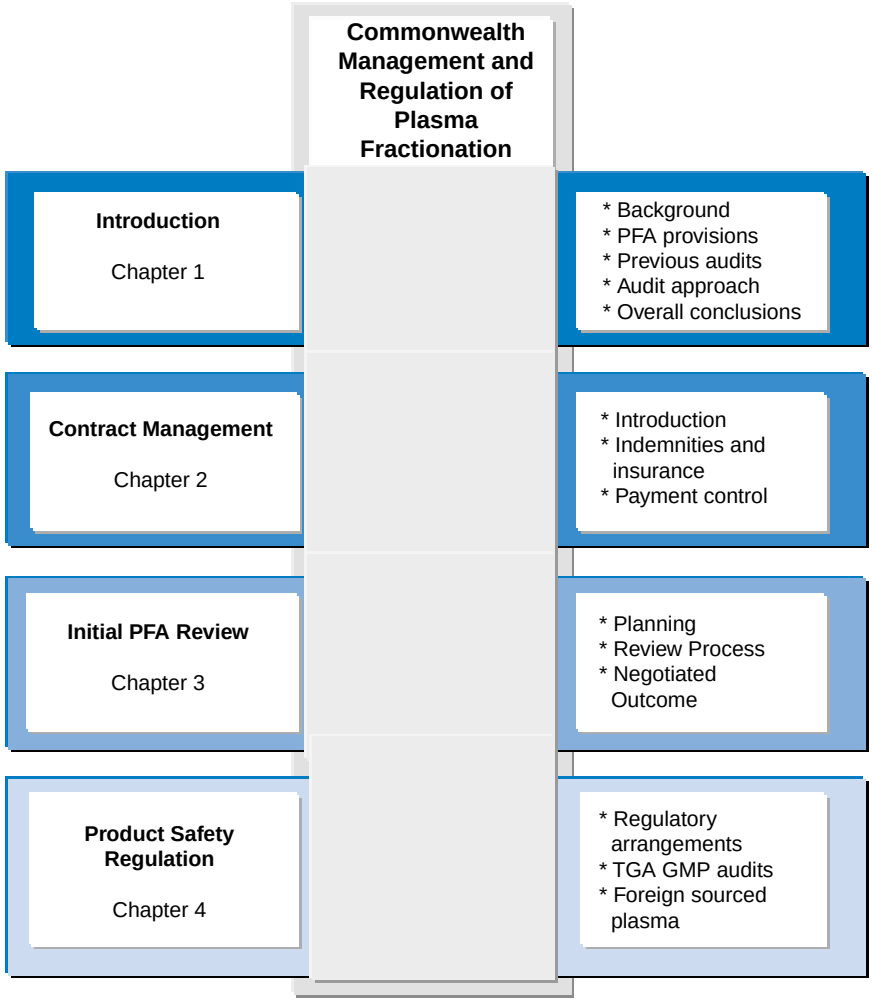
1.20 ANAO engaged the services of the Australian Government Solicitor (AGS) to provide legal advice in relation to a range of issues associated with DHAC's management of the PFA and the associated exposures.

1.22 The audit was conducted in accordance with ANAO Auditing Standards at an estimated cost to the ANAO at the time of tabling of $261 000.

Report outline

1.23 Figure 1.2 sets out the scope of the audit report and its structure. The second chapter of the report discusses DHAC's contract management in relation to the PFA including its management of exposures and financial management. Chapter 3 examines the 1996 review of CSL's cost structure and the prices of its plasma products, which was a requirement of the PFA. Chapter 4 examines Commonwealth product safety regulation of the plasma fractionation.

Figure 1.3
Report Scope and Structure



2. Contract Management

This chapter examines the Department of Health and Aged Care's exposure and financial management associated with the PFA.

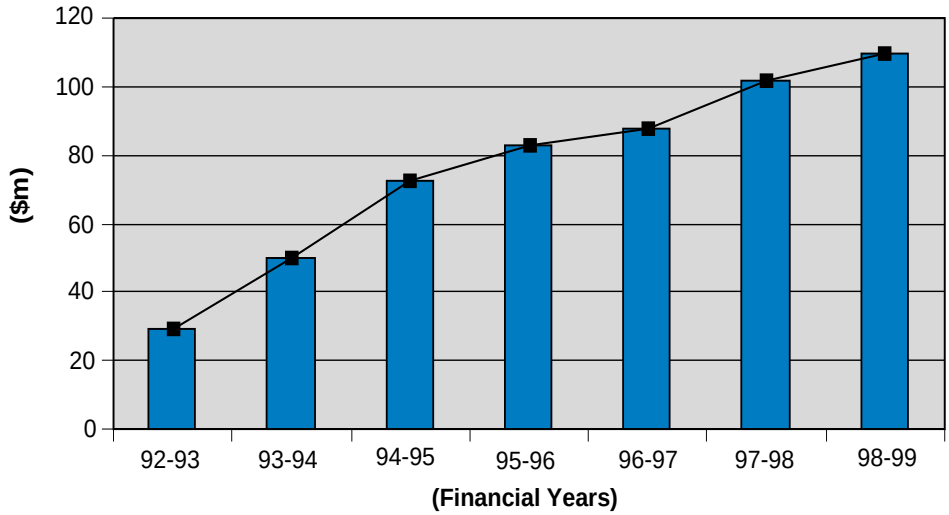
Introduction

2.1 Responsibility for the management of the PFA is currently located within the Acute and Coordinated Care Branch of DHAC. Payments for products produced by CSL are based on a fixed price for each unit of production. Under the contract, two prices are set for each product. One price is significantly higher and 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. The second (lower) price is paid on all production above the threshold level.

2.2 Commonwealth expenditure on CSL's plasma derived products has grown significantly over the last seven years from $29 million in 1992–93 to $109.5 million in 1998–99, an increase of 377 per cent (see Figure 2.1). Reasons for this include a substantial increase in the amount of plasma processed by CSL over the period, and the change in the pricing principles for these products that occurred with the introduction of the PFA on 1 January 1994, prior to CSL's sale.

Figure 2.1

Commonwealth Plasma Products Funding 1992–93 to 1998–99[17]



Source: ANAO analysis of information from DHAC.

[17] Payments shown in nominal dollars. No adjustment has been made for the change in the value of money over time.

2.3 Demand for some of the plasma derived products produced by CSL exceeds supply. Consequently, ARCBS is continually striving to increase the quantity of plasma it collects from donors. In the five years prior to the sale of CSL, the quantity of plasma supplied to CSL by ARCBS grew from 148 013 kg in 1987–88 to 169 588 kg in 1992–93, an increase of 15 per cent. From 1992–93 to 1997–98, the volume of plasma supplied to CSL by ARCBS increased by another 26 per cent to 214 181 kg.

2.4 Commonwealth payments to CSL prior to the PFA consisted of a facility charge (payment for recurrent fixed costs) and a variable component for individual products. Production at this time occurred at CSL's Parkville facility. Parkville prices were the outcome of a non-commercial pricing arrangement as compared to the various risks faced by CSL under the PFA. Commonwealth payments to CSL for plasma fractionated products before January 1994 did not include any allowance for a commercial return on investment.

2.5 The PFA contract was a negotiated outcome between the Commonwealth and CSL. During the 1995–96 audit of the sale of CSL, the then Department of Finance[18] advised ANAO that the key Commonwealth objectives it aimed to achieve in negotiating the PFA were to provide a fully commercial return to CSL; to implement pricing arrangements aimed at improving the efficiency of CSL over the contract period; and to ensure that national interest considerations are satisfied by CSL which would have a continuing incentive to supply products over the period of the contract.

2.6 DOFA and DHAC developed pricing principles to meet the above mentioned objectives. These agreed principles included establishment of a capital cost base for CSL's Broadmeadows' facility; a process for review of product prices; determining minimum product volumes (two-tier pricing structure); date for commencement of new prices (1 January 1994); and the contract period (up to 30 June 2004 plus a five-year option).

2.7 The Broadmeadows facility was designed and built with capacity substantially more than immediate production volumes and to attain very high quality standards for plasma products. These factors added to the cost structure of the facility and were incorporated in the new product prices under the PFA. In 1993–94, there was a 72 per cent increase in payments for fractionated plasma products which reflected the half-year effect of the PFA which commenced on 1 January 1994. The full-year effect of the PFA occurred in 1994–95 when Commonwealth payments for fractionated plasma products increased by a further 46 per cent.

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[18] The Department of Finance and the Department of Administrative Services were reorganised in October 1997 to form the Department of Finance and Administration (DOFA). In this report the Department of Finance will be referred to by its current name and acronym (DoFA).

2.8 The PFA provided for price adjustments on 1 January 1995, and 1 January 1996 to compensate for the effects of inflation. But, to reflect expected productivity gains in the operation of the new Broadmeadows facility, a CPI minus X factor was to be applied. Accordingly, the quantum of the adjustment was to be calculated based on the percentage change over a 12-month period in the Australian Manufacturing Price Index[19] (published for September in the year preceding the adjustment) minus one per cent.[20] Under the PFA there was no price adjustment on 1 January 1995, because the efficiency dividend was greater than the movement in the Australian Manufacturing Price Index. On 1 January 1996, prices under the PFA were increased by 2.6 per cent in line with the above formula.[21]

2.9 The major adjustment to prices occurred on 1 July 1996 as a result of a review of CSL's cost structure and pricing. Prices were increased such that the same volume and mix of products as had been produced in 1995 would have generated a 4.35 per cent increase in revenue.

Market-oriented demand framework

2.10 The collection, manufacture, storage and distribution of domestic plasma products are funded by all Australian Governments. The role of the ARCBS in the plasma products system is funded 40 per cent by the Commonwealth Government and 60 per cent by the State and Territory Governments. The Commonwealth pays for all of the costs of the plasma products manufactured by CSL. These plasma products are provided free of charge to users. ANAO recommended in the 1995 audit report that DHAC consider developing strategies for establishing a more market-oriented demand frame-work for plasma products, having regard to its existing contractual obligations.[22]

2.11 DHAC advised ANAO that:

> *The Department's original position on Recommendation No.11 was that there were considerable difficulties in adopting a conventional market framework where blood donations and blood products were free goods. This remains the position. There is evidence that even internal 'price signalling' could undermine the current voluntary donor system with uncertain consequences for future safety and supply. However,*

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19 Australian Bureau of Statistics Catalogue No 6412.0.

20 The PFA provided that, had the percentage change over a 12-month period in the Australian Manufacturing Price Index been less than one per cent, no adjustment to the contract prices would have occurred.

21 There has only been one increase in prices under the DPA. From 30 June 1995 prices increased 2.6 per cent.

22 Recommendation No.11, Audit Report No.14 1995–96, *Sale of CSL—Commonwealth Blood Product Funding and Regulation,* p.52.

the Department has consistently supported efforts by ARCBS to adopt a more business-like approach to its blood banking operations. The ARCBS is actively participating in the current review by the Australian Health Ministers' Advisory Council into the management and funding of the ARCBS to achieve greater accountability and transparency through output pricing arrangements.

2.12 **Finding:** ANAO recommended in its 1995–96 audit report on the sale of CSL that DHAC consider developing strategies for establishing a more market-oriented demand frame-work for plasma products, having regard to its existing contractual obligations. DHAC has advised ANAO that the Australian Health Ministers' Advisory Council is conducting a review into the management and funding of ARCBS aimed at achieving greater accountability and transparency through output pricing arrangements.

Indemnities and insurance

2.13 During preparation for the sale of CSL, the Commonwealth's business advisors and CSL both advised that Commonwealth indemnification of CSL post-sale was an important prerequisite for CSL entering into a long term agreement with the Commonwealth to fractionate national blood plasma product supplies. The specific rationale for indemnifying CSL was that the Commonwealth requested CSL (both pre- and post-sale) to manufacture and supply blood plasma and pharmaceutical products.

2.14 Under both the PFA and DPA, signed in December 1993, the Commonwealth agreed to indemnify CSL against claims by persons who become HIV-positive or contract an AIDS-related condition or hepatitis through the use of a CSL plasma or diagnostic product sourced from Australian blood or plasma and manufactured during the terms of the PFA and DPA. While in Commonwealth ownership, CSL already had certain Commonwealth indemnities provided to it. These were both formalised and extended in an Indemnity Agreement signed in December 1993. The Indemnity Agreement superseded indemnities provided previously by Ministers. It covers product liability claims arising from the use of relevant CSL products manufactured prior to the commencement on 1 January 1994 of the PFA and DPA. None of the indemnities applies in the case of claims resulting from CSL's culpable negligence.

2.15 ANAO found in the 1995–96 audit of the sale of CSL that, notwithstanding the absence of any financial limits on the

Commonwealth's exposure under the product liability indemnities, DHAC did not commission any actuarial studies to quantify the potential liability of the Commonwealth for product liabilities pre- or post-sale.[23] In evidence to the JCPAA in July 1996, the Department advised that it was not possible to provide the Committee with even a 'ball park' estimate of the Commonwealth's potential exposure under the product liability indemnities issued to CSL.[24]

2.16 Audit Report No.6 1996–97 and Audit Report No.47 1997–98, examined the management of Commonwealth guarantees, indemnities and letters of comfort. Each audit involved a census of Commonwealth instruments of this kind and requested all portfolio departments to provide data on issues such as any payments made on claims against such instruments. ANAO notes that DHAC did not report to ANAO any payments made in respect of the CSL product liability indemnities in the course of these audits. The two audits of the management of Commonwealth guarantees, indemnities and letters of comfort made a number of recommendations aimed at improving agencies' administrative performance in relation to, among other things, the recording and monitoring of these instruments. Nonetheless, DHAC subsequently did not respond in a timely manner to ANAO's request during this audit for details of any payments made on claims against the product liability indemnities granted to CSL. ANAO requested this information in October 1998 but it was not provided to ANAO by the Department until February 1999.

2.17 DHAC advised ANAO that:

> *The implication* [in the above paragraph] *is that the Department did not know how much it had paid in settlements on CSL's behalf and that it took a long time to work it out. The Department knew the value and number of settlements. It didn't have the information tabulated in the manner sought by ANAO, ie the number and value of claims settled per year. The Department took the opportunity to put all the information on the AIDS settlements for both CSL and the ARCBS into one spreadsheet so that any future combination of data could be easily provided. That is what took the time.*

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[23] The Commonwealth's total exposure in relation to blood and blood products also includes its indemnification (through an exchange of letters between State health authorities and Commonwealth Ministers) of the Australian Red Cross.

[24] JCPA Report No.349, *Review of Auditor General's Reports—Public Hearings held on 23 July 1996*, p.12.

2.18 The Department advised ANAO that no claims have been made in respect of persons becoming HIV-positive,[25] or contracting an AIDS-related condition or hepatitis through the use of a CSL plasma product manufactured from Australian blood or plasma since the commencement of the PFA. Payments by the Commonwealth totalling $19.6 million were paid out in settlement of claims from people who contracted HIV/AIDS prior to the introduction in 1985 of a viral inactivation step in the production process for plasma products and effective screening tests for the virus. The Indemnity Agreement for pre-1994 claims is broader than the post sale indemnities included in the PFA and DPA. Accordingly, $2 million has also been paid in settlement of claims from people who received human growth hormone products which were potentially contaminated with Creuzfeld Jakob Disease (CJD) and further such claims are outstanding. There have been no Hepatitis C claims in respect of CSL products.

2.19 In November 1999, CSL advised ANAO that:

> *It should be noted that CSL has not been found to be negligent or otherwise liable in any litigation which proceeded to court (as noted in the Australian National Audit Office Report No.14–The Sale of CSL). The Commonwealth had the conduct of these matters and decided to notionally allocate these payments as between CSL and Australian Red Cross Blood Service (ARCBS) without reference to fault or proof of responsibility of either party. The Commonwealth decided to make these payments on good policy grounds not on the basis of fault. Had there been no Indemnity Agreement, the Commonwealth in all likelihood would still have made these payments on such policy grounds and to support the ARCBS.*

Insurance

2.20 The option of transferring part of the Commonwealth's risk under the product liability indemnities to an insurer was explicitly considered in the development of the PFA and DPA and each of these agreements provide that, at least annually, CSL is required to seek commercial insurance for those risks covered by the product liability indemnities with the Commonwealth liable for payment of any premium associated with transferring the Commonwealth's risks under the indemnities. No insurance cover in respect of any of the risks assumed by the Commonwealth under the product liability indemnities had been obtained by the time the 1995–96 audit was tabled.

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[25] That is test positive for the Human Immunodeficiency Virus, the retrovirus responsible for AIDS.

2.21 Subsequent to the JCPAA's 23 July 1996 public hearing on the 1995–96 audit report, the Department provided the JCPAA with written advice in August 1996 which indicated that CSL had tried annually, since 1987, to obtain reasonably priced commercial insurance cover for both hepatitis and HIV/AIDS claims and had recently succeeded in obtaining limited insurance cover for hepatitis claims. However, cover for HIV/AIDS claims on commercially justifiable terms had still not been able to be obtained. The limited hepatitis cover was obtained through an extension of CSL's product liability insurance policy, requiring the payment of no separate additional premium.

2.22 In October 1996, the Department approached the then Minister for Health advising that CSL had obtained a quote for insurance cover for HIV/AIDS at a premium which the Department considered to be commercially justifiable for the level of cover offered. CSL proposed that, in line with the apportionment of fixed costs specified for the 1996 Initial Review of CSL's Cost Structure, the Commonwealth should meet 90 per cent of the cost of the insurance cover.

2.23 The Department sought the Minister's approval of an annual grant to CSL for the purchase of insurance to cover HIV/AIDS claims that might arise in the post-sale period. The Minister agreed to the Department's proposal that the Commonwealth meet the cost, on an annual basis, of 90 per cent of CSL's premium for HIV/AIDS cover. Subsequently, the Department made premium payments of $22 095 in May 1995 (for part year cover), $63 882 in June 1997 and $63 241 in November 1998 for insurance cover in the name of CSL to cover occurrences in relation to AIDS/HIV.

2.24 Prior to approaching the Minister on this matter, internal departmental legal advice was sought. The Acute and Coordinated Care Branch was advised by the Legal Services Branch that:

> *. . . if it is decided to take up the insurance, the Commonwealth should request a copy of the proposed insurance contract. It would be appropriate to seek inclusion in the contract of a provision for the Commonwealth to conduct any litigation under a suitable arrangement with the insurer. This would be done on the basis that the insurer is only providing a partial indemnity and that the Commonwealth, as the other indemnifier, also has an interest in controlling the litigation.*

2.25 However, ANAO was initially unable to confirm the details of the insurance coverage, the nature of any subrogation arrangements[26], nor the extent of risk transfer from the Commonwealth as a result of CSL obtaining insurance for either hepatitis or HIV/AIDS claims. This was because DHAC did not have, in its records, copies of the relevant CSL insurance policies. The Department subsequently obtained copies of the relevant documents and provided them to ANAO.

2.26 ANAO notes that the 90/10 split of costs agreed to in Schedule B of the PFA in respect of the terms of reference for the 1996 Initial Review, which DHAC agreed should be used to determine the Commonwealth's share of CSL's insurance premium for HIV/AIDS cover, does not reflect the relative volumes of domestic and foreign plasma processed, nor is it the result of any assessment of the relative risks of CSL's processing of domestic and foreign plasma. DHAC advised ANAO that:

> *The apportionment of CSL's premium insurance costs should ideally be based on the relative risks associated with fractionating overseas plasma and domestic plasma. However, as the quality of imported plasma is implicitly the same as domestic plasma, relative risk is immaterial.*
>
> *Other surrogate determinants could be volume of products manufactured overseas and domestically or from an insurer's point of view, the relative risk of claims and likely quantum of legal costs and settlements. The volume of products or plasma fractionated for international clients is confidential and would not be released by CSL and so is not a viable determinant.*

2.27 **Finding:** In October 1998, ANAO requested information on any payments made by the Commonwealth in respect of the pre-sale and post-sale Commonwealth product liability indemnities granted to CSL. The Department advised ANAO that no claims have been made in respect of persons becoming HIV-positive,[27] or contracting an AIDS-related condition or hepatitis (the two conditions for which post-sale Commonwealth indemnity had been provided) through the use of a CSL plasma product manufactured from Australian blood or plasma since the commencement of the PFA.

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[26] In keeping with the provisions of the DPA and PFA, the Commonwealth's interests in respect of claims below the policy excess and above the policy limit on claims are protected in the insurance agreements through provision for the Commonwealth to take over handling of such claim.

[27] That is test positive for the Human Immunodeficiency Virus, the retrovirus responsible for AIDS.

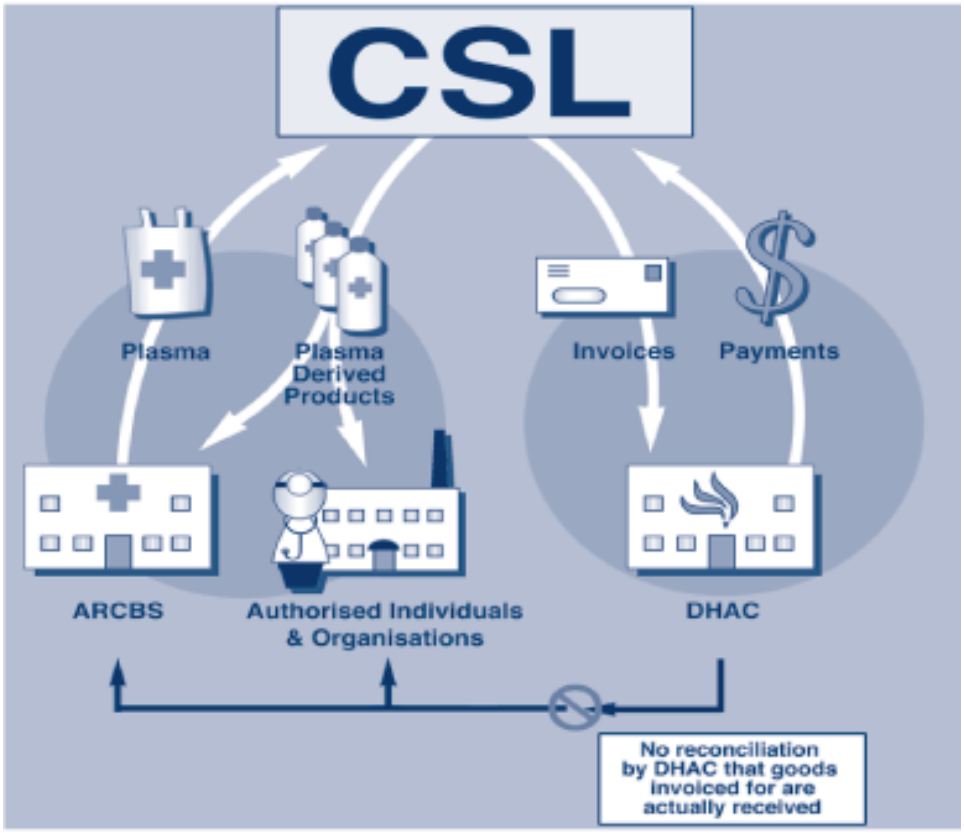
2.28 The Department did not respond to ANAO's request for information on the number and value of claims per year against the pre-sale indemnities until February 1999. DHAC advised ANAO that it did know the total number and value of settlements attributed to pre-1994 production but that it took time to determine the number and value of claims settled per year. Payments totalling some $19.6 million were paid out by the Commonwealth in settlement of claims from people who contracted HIV/AIDS prior to the introduction of effective screening tests for the virus in the mid 1980's.

2.29 DHAC did not have in its records copies of insurance policies obtained by CSL in respect of risks for which it is indemnified by the Commonwealth until ANAO requested it ask CSL for them. This was so, notwithstanding that, in the case of CSL's HIV/AIDS insurance policy, the Commonwealth meets 90 per cent of the premium cost. In light of the indemnities granted by the Commonwealth to CSL, it is important for the appropriate protection of the Commonwealth's interests that DHAC ensure, as part of good risk management, it vets any insurance contract entered into by CSL in relation to those risks for which the Commonwealth has previously accepted liability.

Payment control

2.30 The Department is invoiced on a weekly basis by CSL for product dispatched to ARCBS and authorised individuals and organisations. The Department verifies that it has been billed at the correct price given the level of product manufactured, specified minimum and maximum product quantities and unit prices. It then arranges payment to CSL. Under the PFA, CSL provides the Department with an annual statement of product volumes and prices that the Department then reconciles against the weekly invoices it has received for the year. Figure 2.2 sets out in diagrammatic form how, until recently, the flows of plasma, plasma products, invoices and payments occurred.

Figure 2.2
The product and payment cycle before April 1999



Source: ANAO analysis of information provided by DHAC

2.31 ANAO's 1995–96 audit report which examined the sale of CSL and management of Commonwealth blood product funding and regulation identified that the Department did not have in place an internal control system which could reconcile invoices provided by CSL[28] with recipients' receipt of the products. In response to the November 1995 ANAO recommendation[29] that the Department review its management information system for monitoring payment for these products, the Department advised ANAO that this was currently being addressed by the Department.

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[28] For payments to CSL under both the PFA and the Diagnostic Products Agreement.

[29] Recommendation No.12, Audit Report No.14 1995–96, *Sale of CSL—Commonwealth Blood Product Funding and Regulation*.

2.32 An internal audit report[30] completed by the Department's Audit and Fraud Control Branch[31] in April 1996 also found that procedures adopted for the payment of invoices under the PFA did not include reconciliation of the volumes of products actually received by recipients and the invoices rendered to the Department. Consequently, the report recommended that

> *reconciliation strategies be developed to ensure appropriate control over and accountability for the expenditure of public funds.*[32] *It was noted in the text of the recommendation that it is understood that, in response to a similar recommendation in the report of the ANAO on the Efficiency Audit of the Sale of CSL (tabled 30 November 1995), the development of accountability strategies along these lines is underway.*

2.33 Notwithstanding the recommendations of both the previous ANAO audit report and the Department's Audit and Fraud Control Branch report, and that the issue was again raised by ANAO in the context of the current audit in October 1998, no appreciable progress in developing and implementing appropriate reconciliation strategies was achieved by the Department prior to April 1999. By this time, more than $400 million of Commonwealth funds had been expended under the PFA without the Department implementing procedures to provide assurance that the products for which it was invoiced had been received by the designated recipients.

2.34 In the context of the current ANAO audit, the Department advised ANAO that it has now moved to develop a process for reconciling CSL invoice records with records of deliveries received by the ARCBS. The Department advised ANAO that:

> *The implementation of a reconciliation process had been delayed because the Department was waiting for the new national computer to be installed in ARCBS. However, this has taken longer than anticipated and the Department has therefore initiated a combined electronic/ manual system that hopefully can be fully automated once the ARCBS computer comes on line.*

2.35 By far the majority of product produced under the PFA is provided to ACRCBS for further distribution as required. However, a large number of other individuals and organizations such as doctors, hospitals and

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30 *Final Report on the Review of the Post-Privatisation Relationship between the Department and CSL*, Audit Report, DHAC Audit and Payments Control Branch, April 1996.

31 At the time the branch's title was Audit and Payments Control Branch.

32 Ibid, Recommendation No.2 p.23

pathology laboratories are authorised to receive product from CSL under the PFA. The Department has advised ANAO that work is also under way to develop a method of reconciling CSL invoice records with the delivery dockets of other approved organizations and individuals which are recipients of CSL plasma products.

2.36 In November 1999, DHAC advised ANAO that:

> *Based on experience and on the reconciliation of such delivery dockets as have been received, the Department is confident that the products (particularly therapeutic products) it has paid for have been provided by CSL to authorised recipients. The Department engaged a consultant in September 1999 to undertake a scoping exercise on the invoice reconciliation program. On the basis of that scoping study, the consultant concluded that there was a high level of matching between the products received by the ARCBS and those invoiced by CSL and while a more comprehensive and formalised process was required, there did not appear to be a high risk of mis-payment or fraud. The consultant is now working with the Department to implement a comprehensive sampling methodology that will meet audit requirements for both therapeutic and diagnostic products.*

2.37 **Finding:** There has been an absence of adequate financial controls over payments made by DHAC under the PFA. Between 1 January 1994 and April 1999, DHAC paid out more than $400 million of Commonwealth funds under the PFA without a formal process in place to confirm that the products it was invoiced for had actually been received by the designated recipients.

2.38 DHAC advised ANAO in November 1999 that it had engaged a consultant in September 1999 to undertake a scoping exercise on the invoice reconciliation program. On the basis of that scoping study, the consultant advised DHAC that, *there was a high level of matching between the products received by ARCBS and those invoiced by CSL and, while a more comprehensive and formalised process was required, there did not appear to be a high risk of mis-payment or fraud.*

2.39 ANAO considers that an appropriate corporate governance framework, which includes adequate financial controls, is one of the most effective ways for an agency's management to promote the efficient, effective and ethical use of Commonwealth resources.

2.40 ANAO indicated in its 1995–96 audit report on the sale of CSL that DHAC did not have in place an internal control system which could reconcile invoices provided by CSL with recipients' receipt of products.

Accordingly, ANAO recommended that the Department review its management information system for monitoring payment for products supplied under the PFA. DHAC's November 1995 response to this recommendation was that it was currently addressing the matter. In April 1996, DHAC's Audit and Fraud Control Branch made a similar finding and recommendation. The April 1996 DHAC report noted that in response to the 1995 ANAO recommendation work on this matter was underway in the Department.

2.41 Notwithstanding the recommendations of both the previous ANAO audit report and the Department's Audit and Fraud Control Branch report, and that the issue was again raised by ANAO in the context of the current audit in October 1998, no appreciable progress in developing and implementing appropriate reconciliation strategies was achieved by the Department prior to April 1999. The Department advised ANAO that it has now moved to develop and implement relevant reconciliation processes.

Recommendation No.1

2.42 ANAO *recommends* that the Department of Health and Aged Care enhance its accountability for performance by improving its monitoring of compliance with Departmental audit follow-up procedures to ensure all relevant external and internal audit recommendations are implemented in a timely fashion.

2.43 **DHAC's response** was that it **agrees** with the recommendation. The Department advised ANAO that its Audit Committee had reviewed, on a quarterly basis since December 1997, the actions taken by the Department in response to recommendations of Internal Audit reports. Similarly, since the October 1996 change of arrangements associated with Ministerial reporting on matters raised in Auditor-General's reports, the Audit Committee had reviewed and cleared the Department's responses prior to their submission to the Minister for approval. With the more recent changes to the arrangements for the follow-up of the Auditor-General's reports, with effect from December 1999, the Department's Audit Committee will review actions taken in response to matters raised in the Auditor-General's reports on a quarterly basis, in line with the approach adopted for the follow-up of Internal Audit reports. In line with the recommendation, the Audit Committee will pursue a more rigorous approach to the follow-up of audit reports.

3. Initial Plasma Fractionation Agreement Review

This chapter examines the 1996 review of CSL's cost structure and product pricing required under the PFA including the Department's planning for the review, its role in the review process and the outcome of the review.

Planning

3.1 At the time that the PFA was negotiated and signed in 1993, CSL's Boadmeadows facility was yet to commence full production. Production was still largely occurring at the ageing Parkville facility. Accordingly, prices for CSL's plasma products to be supplied under the PFA were costed on the basis of forecasts of the likely cost structure to apply at the Broadmeadows facility.

3.2 In negotiating the PFA, both the Commonwealth and CSL recognised that there may be significant variations between the forecast costs and the actual costs of production.[33] Accordingly, 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. This Initial Review was to be undertaken by an independent expert appointed by both parties. The PFA provides that, at the conclusion of the Initial Review, prices under the PFA were to be adjusted taking into account 50 per cent of any difference between the forecast costs and the actual costs as determined by the independent expert.

3.3 Schedule B of the PFA forms the terms of reference for the Initial Review and it states that the consultants engaged to undertake the review were to determine the actual cost attributable to domestic production for Calendar Year 1995 and report on the reasonableness of the actual costs incurred by CSL for the year ended 31 December 1995.

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[33] During the 1995 audit, DOFA advised ANAO that*: While a CPI-x discount is being applied for only the first two years and a half years of the facility's operation, it expects productivity gains from either cost reductions or yield improvements to be most evident in the early years of the contract, as part of a settling in period when CSL management would learn how to operate the new technology in the most efficient way. A considerable part of the benefits of productivity gains made in the first two and a half years will also be locked into the pricing structure for the remainder of the contract term, through the Independent Review of costs and prices. While prices will be adjusted by 50% rather than the whole amount of any reductions in costs following the review, such a sharing of productivity gains between the Commonwealth and CSL was considered necessary to give CSL sufficient incentive to achieve a lower cost structure.*

3.4 The assessment of the reasonableness of the actual costs was to include consideration of whether the costs were justified; whether staff levels were appropriate for the operation of the Broadmeadows plant and equipment; and whether there were any material one-off costs that the consultants considered should not appropriately be included in the calculation of actual costs. One of the requirements of Schedule B was that the reviewer have regard to the agreement of the parties that 90 per cent of the fixed costs of production were to be allocated to domestic production (that is, the production paid for through the PFA).

3.5 The consultants were to prepare a written report providing conclusions and the evidence upon which the conclusions were made; prepare a revised operating cost structure for the Broadmeadows facility taking into account 50 per cent of the difference between the forecast and actual cost of each component of the cost structure; and amend the unit prices of plasma products in light of the revised operating structure.

3.6 On 24 January 1996, DHAC issued a select tender for the Initial Review to three accounting firms. The tender brief included the terms of reference for the review (which form Schedule B to the PFA) and also stated that the successful tenderer would be required to enter into a contract with the Department and CSL prior to commencing the review. Tenderers were provided with a review timetable that required that the final report be submitted by 30 April 1996.

3.7 Tenders were received from two firms, both proposing similar fees and charges. The Department and CSL agreed to appoint consultants to undertake the task. The consultants commenced the task on 4 March 1996 without having signed a contract with the Commonwealth and CSL. The Department and CSL reached final agreement on the content of the consultants' contract in early May 1996, following submission of the consultants' final report on 30 April 1996. However, the Department was unable to provide ANAO with a copy of the agreement that had been signed by any of the parties.

3.8 The amount paid to the consultants for the Initial Review was $48 840 including out of pocket expenses. Under the PFA, the Department and CSL were each responsible for payment of half of the cost of the Initial Review. The Department agreed to an arrangement whereby CSL paid the accounts from the consultants and the Department directly reimbursed CSL for its share of the cost. ANAO notes that the invoices rendered by the consultants for the Initial Review were both issued solely in the name of CSL, instead of both CSL and the Department, and therefore it could be interpreted that there was no direct financial relationship between the Department and the consultants during the review.

3.9 The time available to the consultants to undertake the review was significantly reduced because of the delay in issuing the tender brief and then completing the engagement process. In the end, there were less than two months available to undertake the review tasks and settle the final report.

3.10 ANAO notes that at the time of the 1996 Initial Review, management of the PFA rested in a section of what was then called the State Financing Branch. ANAO understands that the Branch's many responsibilities included the negotiation of Medicare Agreements with the State Governments, which was in train at the time. The tasks of the section responsible for the Department's role in the Initial Review included management responsibility for some seven other programs,[34] in addition to grants to the Australian Red Cross and the contracts with CSL in relation to blood products.

3.11 No additional staffing was provided to the Section when it took over responsibility in late 1995 for the management of the CSL contracts from another area (since disbanded) of the Department. In addition, there was a lack of corporate memory available to the contract managers as no Departmental officers who had been involved in the development of the CSL contracts were employed in the relevant Section or Branch. The Department advised ANAO in August 1999 that it had been decided to create an additional section to take sole responsibility for the blood programs.

Reviews

3.12 On 10 May 1999, the Minister for Health and Aged Care announced that he had established a review of the Australian blood banking and plasma production sector. Headed by former Governor-General, Sir Ninian Stephen, the review is to investigate the capacity of the blood system to maintain quality and safety of the blood supply for the future, and consider ways to increase the supply of essential blood products. The review is expected to run about 12 months.

3.13 CSL advised ANAO that, in light of the current review, it had recently commissioned benchmarking of its pricing against major European manufacturers. Prices of the foreign manufacturers were adjusted, where necessary, to take out any component related to the purchase of plasma, as CSL does not pay for the plasma provided by

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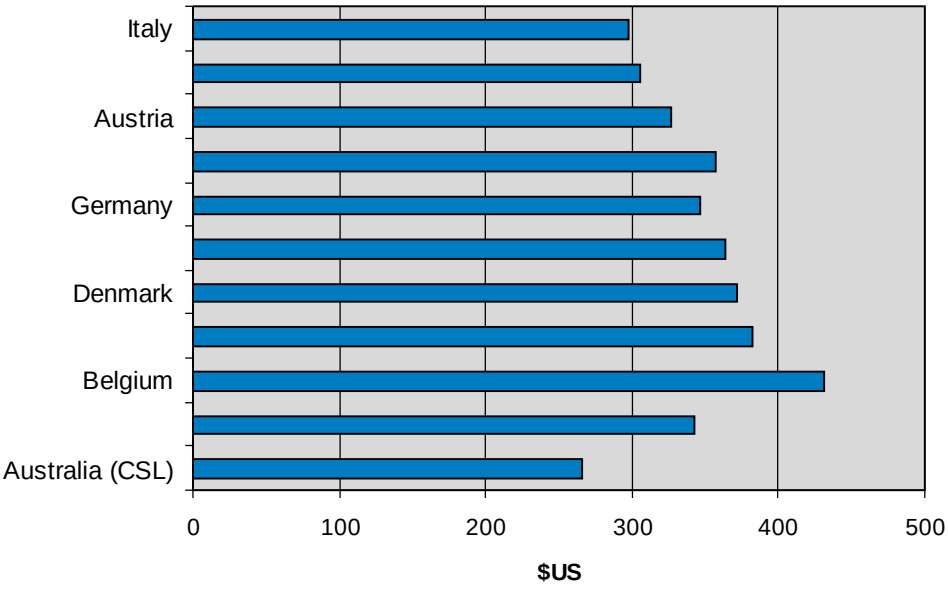
[34] The Commonwealth Dental Health Program, program of Assistance for Survivors of Torture and Trauma; Innovative Health Services for Homeless Youth; Overseas Medical treatment Program; Organ and Tissue Donation programs; Australian Bone Marrow Registry; National Musculoskeletal Medicine Initiative; and broadbanding of selected programs into the Health Care Agreements. Since that time the Section also acquired responsibility for palliative care.

ARCBS from volunteer donors. On the basis of assumptions including industry average yields and an exchange rate of 0.63 AUD:USD; CSL calculated that its current average price (market revenue) per litre of plasma fractionated is $265.22 as compared to a European average of $352.70 per litre. In this circumstance, CSL calculates the prices paid in Australia as 75 per cent of the European average in market revenue per litre. Figure 3.1 shows the country by country comparison of the market revenue per litre of plasma fractionated based on CSL's benchmarking data. The prices have been adjusted to remove any plasma costs, as Australian plasma is provided free of charge by voluntary donors.

Figure 3.1

European Market Revenue per Litre and Current CSL Average Pricing



Source: ANAO analysis of information provided by CSL Limited.

3.14 The initial term of the PFA is to 30 June 2004 but it is extendable to 30 June 2009 at the option of Commonwealth. Given the significance of the fractionation of plasma both in a financial and policy sense, there needs to be adequate and effective planning by DHAC to ensure that the interests of the Commonwealth and the community are appropriately safeguarded. In view of the complexities involved in this area, early consideration will need to be given to resourcing the process to ensure that appropriate consideration is given to the wide range of public policy issues involved, not least whether to potentially extend the contract. In particular, this planning will need to address the question of accessing appropriate expert assistance to facilitate a comprehensive evaluation of the Commonwealth's options.

3.15 **Finding:** DHAC did not take action to initiate the Initial Review, which had to be completed by 30 April 1996, until late January 1996. As a consequence, the consultants did not commence work until March 1996. In this circumstance, the time available to address the extremely complex issues that arose in the course of the review was severely constrained. The Department also failed to execute a written contract with the consultants who undertook the Initial Review.

3.16 The Department advised ANAO that, in late 1995 and early 1996, the area of DHAC responsible for the management of the PFA lacked access to any relevant corporate memory as no Departmental officers who had been involved in the development of the CSL contracts were employed in the relevant Section or Branch. The resources allocated to the Department's management of the PFA were insufficient given the large range of other responsibilities also allocated to the relevant managers. As a consequence, the complexity of the PFA and the Initial Review were not appreciated by the responsible departmental mangers, and appropriate planning for the Initial Review was not undertaken. DHAC advised ANAO in August 1999 that it was moving to create a new Section that will be responsible for the management of the Commonwealth's contracts with CSL and other blood programs.

Recommendation No.2

3.17 ANAO *recommends* that the Department of Health and Aged Care:

(a) for future engagements of consultants, ensure that a formal written contract is signed prior to work commencing and that a copy is retained by the Department;

(b) commence early planning for the expiry of the initial term of the PFA contract to ensure that the Commonwealth can advise CSL Limited of its preferred position by May 2002; and

(c) ensure that, in considering options for future supply of plasma products following the expiry of initial term of the PFA, the Department seeks appropriate expert legal, financial and product advice before entering into any contract negotiations.

3.18 **DHAC's response** was that it **agrees** with the recommendation.

Review process

3.19 The review process set out in the PFA is in the nature of an arbitration, that is an independent party is appointed by the parties, to hear the parties and impose a binding decision on them.

3.20 ANAO received legal advice from AGS that the process actually adopted by the consultant, the Department and CSL was in the nature of mediation, that is, a process of assisted negotiation where the parties with the assistance of a neutral party (in this case the consultants) systematically isolate disputed issues in order to develop options, consider alternatives and reach a consensual agreement which will accommodate their needs. The consultant identified issues which it then put to the parties for resolution before incorporating the agreed position on each issue into the 'actual cost' structure for Calendar Year 1995. This represented a significant departure from terms of the PFA and altered the Commonwealth's risk profile in relation to the 1996 Review.

Figure 3.2

CSL's perspective on the review process

While it is recognised that the PFA originally provided for the Independent Expert to make its own determinations of the cost issues under the Initial Review without the need for the parties to reach an agreement on specific issues, the facts are that:

- while the skills required of the independent expert were predominantly accounting and financial in nature, and it was contemplated by the PFA that a chartered accountant would be appointed, some matters for consideration did require knowledge of some complex plasma production issues (such as in relation to the chromatographic gels), and it was not possible for a chartered accountant to make his or her own independent determination;
- given the new and leading edge nature of the Broadmeadows plant, no relevant benchmarking of information on costs was available from other plants anywhere in the world;
- given the circumstances in which the PFA was originally agreed, inevitably there were cost issues which arose over the first two years which were not previously contemplated and required special consideration by the parties;
- the drafting of some of provisions of the PFA was unclear, and it was logical and appropriate for the expert to seek clarification from the parties as to their intention; and
- in any event, it is always open to the parties to any contract to agree changes to the contract (such as price review clauses) or agree the way in which it is to be interpreted. In this case, both the Department and CSL were satisfied with the process and outcome.

In view of the above, we consider that the review process under which the parties reached agreement on certain cost issues was entirely appropriate.

Source: CSL Limited, 24 November 1999.

3.21 AGS advised ANAO that the consultants did not act in accordance with the requirements of the relevant provisions of the PFA[35] in conducting the Initial Review. Clause 3.4.5 of the PFA states that, in conducting the Initial Review and preparing his report, the independent expert must do so in accordance with the Terms of Reference contained in Schedule B. AGS' opinion is that it was not the obligation of the parties to reach agreement, it was for the consultants to arrive at an assessment based upon a review conducted in accordance with Schedule B of the PFA.

[35] Clause 3.4 and Schedule B of the PFA.

3.22 AGS further advised ANAO that the Final Report provided by the consultants on 30 April 1996 did not satisfy the requirements of the PFA, including in regard to providing evidence upon which conclusions have been made and reporting on whether the actual costs incurred by CSL in the year ended 31 December 1995 were reasonable and justified, and that staff levels were appropriate for the operation of the Broadmeadows plant and equipment.

3.23 DHAC advised the ANAO that:

> *In September 1999, the Department sought a legal opinion on the same aspects of the Initial Review as sought by the ANAO from the AGS. Among other things, the opinion provided to the Department concluded that where the contract was ambiguous or unclear or relied on interpretation, it was open for the independent expert to have the parties resolve such matters by agreement.*

3.24 In November 1999, the consultants advised ANAO that, whilst they did not dispute the AGS' opinion that the review was not performed in accordance with the provisions of the PFA, the consultants considered they were not obligated to act in accordance with the PFA. The consultants advised that, by virtue of having undertaken the review in terms of a project charter they had prepared and agreed with CSL and the Department, they had acted within and in accordance with their contractual obligations. ANAO notes that the Department did not secure a written agreement signed by the consultants, CSL and itself for the conduct of the Initial Review by the consultants. The project charter prepared by the consultants was not signed by any of the parties. AGS has advised ANAO that many of the matters set out in the project charter were inconsistent with clause 3.4 and schedule B of the PFA.

3.25 The consultants prepared a draft Final Report which they provided to the Department on 29 April 1996. In this draft report, the consultants clearly outlined the process actually undertaken whereby, for the most part, issues had been identified and then referred to DHAC and CSL for resolution before incorporating the agreed position into the cost structure. On 30 April 1996, DHAC sent a facsimile to the consultants requesting a range of amendments. The consultants provided a further draft of the

Final Report the same day that had been revised along the lines requested by DHAC.[36] The consultants' accompanying facsimile noted:

> *Attached is a draft copy of our final report. I have made the required adjustments, however we note that the report no longer complies with the requirement to provide "conclusive evidence upon which the conclusions have been made". We do not believe that this is possible without either referring to the previous reports and minutes or detailing each issue within this report. Could you please indicate by return fax that the current format of the report satisfies our requirements for this engagement.*

3.26 DHAC responded to the consultants advising that '*the draft is acceptable to the Department'*. The Final Report was then provided to CSL and DHAC the same day, 30 April 1996.

3.27 In response to a range of questions that ANAO had put to DHAC about its actions in connection with the 1996 Initial Review, the Department advised ANAO that:

> *The Department's expectations were that the independent expert would proceed largely on his own endeavours although as previously indicated, this was not seen as an absolute requirement. When the extent of the problems faced by* [the consultants] *with inconsistencies and benchmarking became clear, the parties had two choices. The first was to cancel the contract with* [the consultants] *and re-tender. The second was to work within the existing constraints to deliver a reasonable result for both CSL and the Commonwealth, whilst adhering as closely as possible to the independent intent of the terms of reference.*[37]

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[36] The Department's facsimile of 30 April 1996 noted: ……*while we have no problems with the basic conclusions of the report, the new price schedule etc., we believe that there is no requirement for the report to focus on the mediation role played by the independent expert, nor for the report to detail the process of resolution of the various ambiguities that arose during the course of the review. In our view the current report implies that the independence of the reviewers may have been compromised by relying on the parties to resolve these ambiguities. We believe that it is important that* [the consultants] *are seen to comply with the requirements of the contract to have the final say in resolving contentious issues. Such suggestions as may have been made by the parties to resolve issues were in their finality for* [the consultants] *consideration. It is important that the fact that they were accepted should not be presented as an abrogation of* [the consultants] *arbitration responsibilities.*

[37] The Department further advised ANAO that *throughout the course of the review, the Department required the independent expert to deliver conclusions based on the best available evidence. At the end of the day, the Department and CSL accepted that the process had to be partly modified to ensure that an acceptable outcome was achieved within the time limit stipulated in the PFA. Moreover, the Department is satisfied that the outcome was reasonable as measured against its objectives at the time.*

3.28 **Finding:** ANAO's legal advice is that the review process actually undertaken for the 1996 Initial Review 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 the Department's agreement, was in the nature of a mediation.

Negotiated outcome

3.29 The review process laid down in the PFA required only that CSL and the Department accept the consultants' decision on the prices payable under the PFA from 1 July 1996, based on the consultants' report (including evidence for their conclusions). However, what actually transpired was a process whereby the consultants identified a range of material issues relating to the calculation of the revised actual cost structure for domestic plasma fractionation and then referred them to the Department and CSL for resolution.

3.30 The Department advised ANAO in July 1999 that it had the following objectives in mind in those situations during the review that required consultation and agreement between the Department and CSL:

- *to maintain an on-going, nationally self-sufficient supply of plasma products by ensuring, inter alia, that CSL remained a viable entity within the domestic blood sector—this objective being consistent with the policy of the Government of the day and successive governments;*
- *not to compromise the Government's broader privatisation policy by putting the initial price review process at risk over relatively small differences in outcome;*
- *to adhere to the basis concept in the PFA, that the review had to deliver an outcome that was reasonable to both parties, that is, the Commonwealth had to take a balanced approach;*
- *to take reasonable steps to reduce the likelihood that CSL would seek future price reviews to redress issues that it considered were unfairly dealt with during the review, particularly issues where the 'right' answer was not clear cut; and*
- *to negotiate and trade-off in a framework where any increase in Commonwealth outlays for plasma products did not exceed a point beyond which the Department would have been obliged to terminate the review process.*

3.31 The Department advised ANAO that it had calculated that the possible outcomes to the negotiation of the issues identified by the consultant as requiring resolution. These ranged from on one extreme (acceptance by the Commonwealth of all of 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, on the other extreme, (rejection by the Commonwealth of all of CSL's claims) a **decrease** in annual Commonwealth outlays of $1.4 million or 1.83 per cent. The outcome of the negotiation process with CSL was an **increase** in annual Commonwealth outlays for the 1995 level of products of $3.5 million or 4.35 per cent.

3.32 DHAC advised ANAO that:

> *The Department notes that* [the ANAO audit report] *does not conclude that the overall outcome of the price review was unreasonable. The Department's view is that an outcome in the middle of the range of likely outcomes represents a reasonable outcome in the circumstances.*

3.33 ANAO has not had access to the complete evidentiary base of information necessary to form a judgement as to the reasonableness for the Commonwealth of the outcome of the Initial Review.

3.34 The outcome of the negotiation process with CSL involved acceptance by the Department of a total net increase in fixed costs (90 per cent of which is allocated to domestic production funded under the PFA) of $14.6 million and a total net reduction in variable costs (68 per cent of which is allocated to domestic production funded under the PFA) of $3 million. Accordingly, the total 'actual' costs for Calendar Year 1995 determined by the Initial Review process was $77.7 million as compared to the forecast of $66.2 million.

3.35 The PFA provides for 50 per cent of the difference between the forecast and 'actual' variable costs (half of the $3 million decrease being $1.5 million) and the forecast and 'actual' fixed costs (half of $14.67 million being $7.3 million) to be taken into account in determining revised prices following the Initial Review. The parties agreed during the review process that 68 per cent of the variable costs were actually attributable to domestic production, and the PFA specifies 90 per cent of fixed costs were to be allocated to domestic production in the review. Accordingly, a decrease in variable costs of $1 million (68 per cent of $1.5 million) and an increase in fixed costs of $6.6 million (90 per cent of $7.3 million) were taken into account in calculating the product prices to apply from 1 July 1996.

3.36 During the negotiation process, the Department agreed to significant variances from the forecast costs including:

- for depreciation—an increase of some $9 million or 47 per cent;
- for labour—an increase of some $5.7 million or 52 per cent; and
- for fixed materials—through the removal of chromatographic gels from the asset base and inclusion in the fixed materials category, an increase of some $876 000 or 95 per cent.[38]

3.37 Significant variances to the forecast costs that CSL agreed to have excluded from the 'actual' costs for Calendar Year 1995 included:

- for interest expense[39]—inclusion of an amount of $2.4 million (the consultants identified in their 10 April 1996 report that inclusion of this cost was not supported by the methodology used to develop the forecast costs and that it was not clear that the terms of reference of the contract would allow these costs to be included in developing new schedule prices);
- for insurance costs—actual insurance costs for Calendar Year 1995 when calculated using the forecast methodology were $1 083 220 which was some $383 000 less than the forecast amount. CSL argued initially that an amount, at least enough to bring the costs up to the forecast of $1 466 000, should be included in recognition of self insurance costs; and
- for restructuring—inclusion of an amount of $187 000 representing a percentage of corporate cost allocated to the Broadmeadows facility by the company (the consultant also identified that inclusion of this cost was not anticipated by the methodology used to develop the forecast costs).

3.38 In November 1999, CSL provided the following comments to the ANAO (see also Appendix 1 (A):

> *CSL had two major concerns with the PFA concluded with the Commonwealth in 1993.*
>
> - *There would be cost relief from upward movements in the Australian Manufacturing Price Index (MPI). CSL is only entitled to price increases on this basis if the MPI increases by at least 1% in 12 months, and this has only occurred once in 1995, despite increases in manufacturing costs at the Broadmeadows plant. For example, labour costs have increased on average 4% p.a. as a result of Enterprise Agreements.*

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[38] In their 10 April 1996 report, the consultants identified the inclusion of these additional costs for chromatographic gels as the main reason for the difference between the forecast and the actual costs of fixed materials. However, ANAO notes that the total increase in the fixed materials cost category $3.5 million. Excluding the $876 000 for chromatographic gels, there was still an increase of $2.6 million over the forecast of $926 000. From the papers available to ANAO, it was not possible to identify why this was so.

[39] DHAC advised ANAO in July 1999 that CSL had assured the Department that no part of the Broadmeadows facility was encumbered. This is a requirement of the PFA and the *Sale of CSL Act 1994*. CSL had advised the Department that the interest was incurred in the normal business process of securing capital.

- *The Initial Review was only a cost review with no scope for any margin increases. In addition, there was a severe limitation on recovering any major cost increases. The PFA provided that CSL would only receive 50% of any additional domestic costs claimed–and only keep 50% of any savings.*

  Both concerns have been realised. In the circumstances of the Initial Review, CSL's allowed costs for the 1995 year were some $77.7m compared with the forecast made in 1993 of $66.2m. Consequently, CSL was allowed price increases representing $5.5m and had to absorb the balance of $6m p.a. This effect is substantial over the remaining eight years of the PFA. It should also be recorded that as a result of the Initial Review, CSL received a price increase of 4.35%. This means that under the PFA, CSL is required to hold its prices constant for current products from June 1996 to 2004 (and possibly 2009) subject only to the possibility of MPI increases. We wonder how many other advanced manufacturers will be able to hold prices constant for this period.

3.39 The role actually undertaken by the Department, as a result of the decision to depart from the process as set out in the PFA and to instead become an active participant in a mediated negotiation process, was significantly more demanding than that originally anticipated when the PFA was developed and the review process initiated. Nevertheless, the Department did not seek any expert assistance of its own to inform its participation in the negotiation with CSL.

3.40 **Finding:** The PFA provided for an independent expert to review CSL's costs in 1995; provide evidence of the reasonableness of those costs; and, if necessary, adjust the price schedule. The expert's decision was to be binding on both the Department and CSL. However, at a critical point in the process, the reviewer depended on a negotiated outcome between the parties. At no time during the Initial Review Process did the Department 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.

3.41 ANAO notes that these decisions were made on the basis of the limited in-house commercial expertise available to the Department, greatly increasing the risk that the Department was not able to adequately protect the Commonwealth's interests given that the other party to the negotiation possessed a range of advantages including:

- direct access and control over the relevant financial and operational data on this unique fractionation facility;

- in-house experts with the relevant industry knowledge; and
- the commercial understanding necessary to successfully undertake such a material negotiation process.

Depreciation

3.42 The total historical cost of assets as at 31 December 1995 was calculated by the consultants to be $246.2 million, an increase of $18.7 million over the forecast of $227.5 million. The Department advised ANAO that it accepted CSL's explanation that this increase in the asset base over the forecast related primarily to significantly higher than expected costs in validating the new plant's processes and in meeting regulatory standards.

3.43 The principal reason for the large increase in depreciation expense was that the PFA required a different methodology be used to calculate depreciation for the review process than had been used in developing the forecast. In preparing the forecast, depreciation had been calculated using differing rates of depreciation for different asset classes. The factory buildings were assumed to have a 40-year life and were depreciated at 2.5 per cent per annum while plant and equipment was depreciated at 10 per cent per annum. This was reflected in the prices paid by the Commonwealth between 1 January 1994 and 30 June 1996.

3.44 The PFA[40] required that, for the purposes of the review, the depreciation expense to be used in determining actual cost for the year ended 31 December 1995 was to be based on the assumption that all assets owned at 31 December 1995 will be depreciated on a straight line basis such that their value at 30 June 2004 (that is the expiry date of the initial term of the PFA) is zero. This results in a depreciation rate of some 12 per cent per annum for all asset classes (including land). This contrasts with the methodology used to develop the forecast costs as described above.

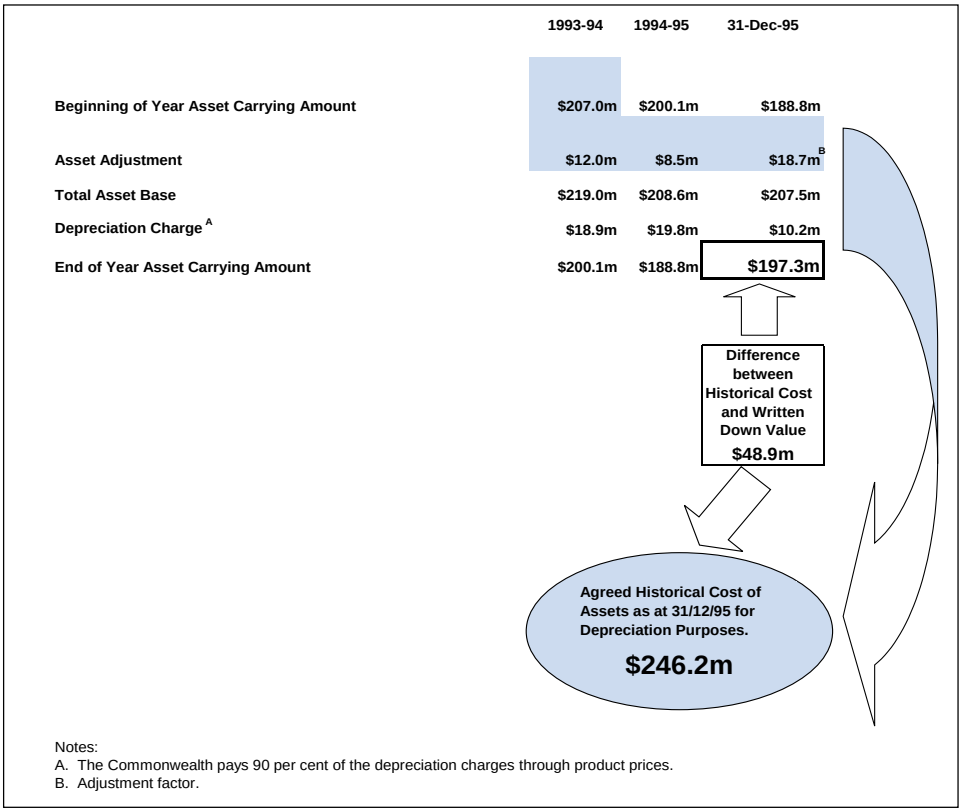
3.45 Prices paid by the Commonwealth for products supplied under the PFA Between 1 January 1994 and 30 June 1996 were set such that 90 per cent of the depreciation expense on assets in those years as calculated by the forecast would be recovered by CSL. The PFA provides for this notwithstanding that only about 68 per cent of the Broadmeadows plant's through-put was domestic plasma in 1995.

[40] Clause 4(d) of Schedule B to the PFA.

3.46 The forecast was developed taking into account an opening balance of $207 million in assets and planned capital expenditure in 1993-94 and 1994-95 of $12 million and $8.5 million respectively[41]. Figure 3.3 below sets out a comparison of the written down asset value and the rebased historical costs agreed between CSL and the Department in 1996.

Figure 3.3

Comparison of Asset Value as at 31 December 1995.



Notes:
A. The Commonwealth pays 90 per cent of the depreciation charges through product prices.
B. Adjustment factor.

Source: ANAO analysis derived from PFA contract and 1996 Initial Review working papers.

3.47 The consultants calculated that the forecast depreciation amount for the 1995 Calendar year was $19.75 million. In this circumstance, CSL would have received back as part of the prices paid for products under the PFA some $35 million in respect of depreciation for calendar years 1994 and 1995. The PFA is silent on whether the written down value, market value or historical cost of the assets owned at 31 December 1995 should be the starting point for depreciation for the 1995 Calendar Year. The review consultants identified that CSL had calculated the depreciation

[41] For the remainder of the PFA the forecast presumed capital expenditure of some $6 million per annum.

amount to apply as a result of the 1996 Initial Review on the basis of the full historical cost of all assets owned at 31 December 1995 ($246.2 million). The consultants' advice to the Department and CSL on 10 April 1996 was:

> *To use the actual historical cost ignores that these assets have already been utilised and depreciated in value since their initial acquisition. This depreciated value has already partly been charged in past operations of the division* [the Bioplasma Division of CSL, which produces the product, supplied under the PFA].

3.48 The Department accepted CSL's approach, without seeking its own appropriate expert legal and accounting advice, to value the assets at their full historical cost. Departmental officers expressed concerns about this issue in a paper sent to the consultant on 19 April 1996. However, in July 1999 DHAC advised ANAO that it had accepted CSL's interpretation to be correct because:

> *notwithstanding the Department's original concerns about the depreciation expense, the weight of evidence suggests that the parties who drew up the original terms of reference for the Initial Review had a specific intention in mind that was not open to subsequent change by the independent expert or the parties to the Agreement. It was not a matter of seeking legal or accounting expertise; it was a matter of interpretation. In light of the evidence and the arguments, the Department considered the use of historical cost was intended. In the event, the Department weighed up the impact of accepting historical cost on the bottom line and given the trade-offs against interest charges and insurance costs*[42]*, and the fact that the net increase in Commonwealth outlays was below 5 per cent, the Department considers the outcome to have been reasonable.*

3.49 ANAO notes that, if it was clear to the Department that the issue of depreciation revolved around interpretation of the contract, then the need to seek legal assistance in interpreting the contract requirements should also have been clear.

3.50 The depreciation figure for Calendar year 1995 included in the 'actual' cost structure as a result of the Initial Review was calculated by dividing the historical cost of assets owned at 31 December 1995, $246.19 million by 8.5 years to give an annual depreciation figure of $28.96 million. The increased costs relating to depreciation to flow through to prices under the PFA from 1 July 1996 were then calculated

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[42] CSL had initially claimed interest costs of $2.4 million which were not included in the forecast and inclusion of some additional $500,00 in insurance costs not contemplated in the forecast methodology. The outcome of the negotiation process was that the parties agreed that the revised cost structure would not include these amounts.

from this starting point as opposed to the written down value of historical costs (see Figure 3.3).

3.51 Prices paid by the Commonwealth for products supplied under the PFA between 1 January 1994 and 31 December 1995 returned to CSL some $35 million[43] in depreciation charges. The PFA provided that 50 per cent of any increase in costs over those forecast were to be taken into account for the purposes of calculating the revised prices to apply from 1 July 1996. The Department agreed to rebase CSL's assets as at 31 December 1995 to their full historical cost. The outcome of this was that some $35 million which CSL had received in respect of depreciation on its assets in 1994 and 1995 was added back into the total asset base value. Under Schedule B of the PFA, half of this amount, some $17 million, was then taken into account in deriving the prices to be paid under the PFA from 1 July 1996 over the remaining eight years of the contract. Accordingly, of some $35 million in depreciation charges previously reimbursed by the Commonwealth through product prices paid in 1994 and 1995, some $17 million will be effectively double-counted in the derivation of the product prices paid by the Commonwealth over the term of the PFA.

3.52 **Finding:** Prices paid by the Commonwealth for products supplied under the PFA between 1 January 1994 and 31 December 1995 returned to CSL some $35 million in depreciation charges. The PFA provided that 50 per cent of any increase in costs for Calendar Year 1995 over those forecast were to be taken into account for the purposes of calculating the revised prices to apply from 1 July 1996.

3.53 The review consultants identified that CSL had calculated the depreciation amount to apply as a result of the 1996 Initial Review on the basis of the full historical cost of all assets owned at 31 December 1995 ($246.2 million). The Department accepted CSL's approach, without seeking its own appropriate expert legal and accounting advice, to value the assets at their full historical cost as opposed to their written down value. The outcome of this was that some $35 million which CSL had received in respect of depreciation on its assets in 1994 and 1995 was added back into the total asset base value. Under Schedule B of the PFA, half of this amount, some $17 million, was then taken into account in deriving the prices to be paid to CSL from 1 July 1996 and will be effectively double counted in the derivation of product prices over the term of the contract, notwithstanding any other factors which may have been taken into account in determining the prices.

[43] The figure of some $35 million represents 90 per cent of the forecast depreciation charges for 1994 ($18.9 million) and 1995 (19.8 million). The PFA provided that 90 per cent of fixed costs were allocated to domestic production and so recoverable through product prices under the PFA.

3.54 In November 1999, CSL provided the following comments to the ANAO regarding the issue of the treatment of depreciation in the Initial Review (see also Appendix 1 (B):

> *In the case of depreciation, the PFA was explicit on the write-off period to be used, namely 8.5 years, but was not explicit on whether this was to be applied to the historical cost or written down value of the assets at December 1995. Whilst we acknowledge that the wording of the relevant clause in Schedule B was open to interpretation, we consider it is clear that the PFA contemplates a different model from that used by [the adviser who prepared the forecast] and that the 8.5 year depreciation was to be applied to historical cost. The Department also agreed that this was the intention. ... ...*
>
> *The use of this historical cost model in the PFA was the principal reason behind the difference between the original forecast cost of $19.8m and the final amount claimed of $29m. We also note that after consideration of all factors surrounding the PFA, including a review of the underlying intentions by both parties, the Department and CSL concurred with the approach adopted. We have already outlined the circumstances relating to the PFA and the Initial Review interpretation. We consider that the above demonstrates the spirit of the process which lies at the heart of the Initial Review and its special purpose clauses included in Schedule B. ... ...*
>
> *On the basis of the above, we refute totally the allegation that CSL will receive a double payment from the Department over the term of the PFA, due to the use of the historical cost convention. We have demonstrated above that the $17.8m in question was not double claimed and that the interpretation of the Schedule B depreciation clause was "in hindsight" a very accurate way of forecasting what actually is occurring. Unfortunately for CSL, we only recovered 50% of our depreciation claim (some $4.1m p.a.), which over the remaining life of the PFA amounts to some $32.8m. In our view the reverse of the ANAO's statement is true–the Department benefited to this extent.*

3.55 In November 1999, DHAC also provided comments to the ANAO regarding the issue of the treatment of depreciation in the Initial Review (see also Appendix 1 (C):

> *The Department's view in relation to the conduct of the initial pricing review under the PFA is that a reasonable outcome was obtained in the circumstances. Given the nature of the pricing structure and the*

number of factors to be taken into account, the Department believes that the consideration of individual elements, such as depreciation, within this framework should have regard to the overall outcome of the initial review.

In this context, the Department has an alternative view to that contained in paragraph 19 of the Summary of the proposed report. The Department considers that the PFA is ambiguous and uncertain with respect to the approach to depreciation, and that the approach taken by the parties to the contract was one reasonably open to them under the PFA. This view is supported by expert legal advice obtained by the Department, and provided to the ANAO.

The historical cost of assets on hand at 31/12/95 was $246 million of which the estimated domestic proportion was $221 million. The Department believes that the intention was that this amount was to be recovered over the full period of the contract (1/1/94 to 30/06/2004). Advice from the Department's accountants is that projections indicate that $219 million will be recovered over the period of the contract compared to $221 million (some $2 million less than intended). This means that there is no double-counting.

For the ANAO's finding of double-counting to be valid, the amount recovered for domestic production through depreciation would have to be $202 million ($219 million above less $17 million). This is $19 million less than the estimated domestic proportion of the actual asset base. This $19 million is reconcilable as the $2 million underestimate above plus the $17 million double-counting.

The Department does not believe that attributable cost increases were double counted by the Commonwealth over the term of the PFA. This view is supported by expert accounting advice provided to the Department on this issue. An extract of the accounting advice has been provided to the ANAO, with the full accountant's report to be provided to the ANAO when finalised.

The Department took a conscious decision on the depreciation issue, which was consistent with the overall approach of reaching a favourable outcome for the Commonwealth. In doing so the Department considered that the aim of the review was to establish new and reasonable prices (having regard to the Commonwealth's overall health objectives and CSL's commercial requirements), and not to put in place a regime that keyed primarily off costs.

3.56 **ANAO Comment**: The Department's view that there has been no double-counting of depreciation does not accord with that of the ANAO. The Department and CSL agreed in 1996 to rebase the Broadmeadows asset carrying costs to their historic cost of $246.2 million (see Figure 3.3) as compared to continuing to apply the written down carrying amount of the assets (some $197 million). The Department's agreement to use rebased historic cost means that more than $17 million in depreciation costs previously recovered by CSL through product prices in 1994 and 1995 will be again recovered through product prices paid by the Commonwealth over the final eight years of the contract.

3.57 The Department agreed to a process for the 1996 Initial Review which was not in accordance with the requirements of the PFA. ANAO notes that DHAC advises that *it took a conscious decision on the depreciation issue, which was consistent with the overall approach of reaching a favourable outcome for the Commonwealth.* However, the PFA provided for an independent expert to review CSL's actual costs in 1995; 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. The Department agreed to negotiate directly with CSL instead of relying on the independent expert, as provided in Schedule B of the PFA. The consultants engaged to undertake the 1996 Initial Review did not provide in their final report an assessment that the costs reviewed were reasonable. At no time during the negotiations with CSL did the Department obtain its own professional assistance to inform its decisions on what were extremely complex commercial and technical issues, such as determining the appropriate carrying value of the asset base. The quantum of funds involved with the depreciation charge over the life of the contract required the Department to be fully informed of the financial implications for the Commonwealth of any decision it made in this regard.

Labour costs

3.58 A second area of material variation between the forecast costs and the costs as determined by the Initial Review related to labour costs. Labour costs increased by $5.7 million or some 52 per cent over the forecast from almost $11 million to $16.7 million. Staff numbers were 117 people and 58.5 per cent more than forecast.

3.59 The terms of reference for the Initial Review as set out in Schedule B of the PFA specifically required that the independent expert engaged to undertake the Initial Review assess the reasonableness of costs, including whether the costs were justified and the staff levels appropriate for the operation of the Broadmeadows plant and equipment. The consultant who undertook the Initial Review bid for the project on the basis that it would undertake such an assessment based on benchmark data and professional judgement.

3.60 However, on 10 April 1996, the consultant advised the Department and CSL that it had been unable to obtain any benchmark data on plasma fractionation plants internationally, nor was it able to usefully compare the experience of the previous CSL plant at Parkville with that of the new plant. The consultant's final report provided on 30 April 1996 noted this and stated that, within these limitations, its review was confined to comparing the actual costs incurred at the Broadmeadows plant with the forecast costs that were developed for the PFA. As a result, the issue of the reasonableness of the large increase in labour costs was negotiated by the Department directly with CSL.

3.61 The Department noted its concern about the reasonableness of the large increase in staffing levels in a discussion paper prepared on 19 April 1996 to outline issues the Department wished to raise following the 10 April 1996 meeting between the consultant and the parties. The Department stated that:

> *while it is accepted that the forecast is just that, an estimate, the increase seems excessive. The Department has noted the comments of* [CSL's expert][44] *in relation to the efficiency of the Broadmeadows plant, but nonetheless wants the independent expert to report on the reasonableness of staff increases and the salary rates before it can make a judgement. Alternatively, the parties may reach a mutually agreeable compromise without the need for the independent expert to formally assess the reasonableness of the labour costs.*

3.62 As outlined above, the consultants did not report to the Department, or in their Final Report, on the reasonableness of the very large increase in labour costs. Instead, they confined their activities to comparing the actual costs incurred at the Broadmeadows facility with the forecast costs that were developed for the PFA and providing to the parties a summary of the reasons advanced by CSL for the increases. The consultants' Final Report did not include any details of the rationale for the increased costs.

3.63 According to the consultants' 10 April 1996 report, some $4.6 million of the $5.7 million increase in labour costs was due to the increase in staff numbers. The remaining major additional costs related to reclassification of staff into different bands than those anticipated in the forecast ($212 000); wages increase due to enterprise bargaining ($400 000); and an annualisation error in the forecast of $133 000.

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[44] In October 1995, an expert on plasma fractionation who had also been engaged during the sale process for CSL, provided a report to CSL which, among other things, commented on the appropriateness of the staffing levels of the Broadmeadows plant as it was operating at that time.

3.64 The forecast was calculated on anticipated staffing of some 200 people. Actual staff numbers in 1995 was 317. The increases in staff numbers[45] occurred in the production, engineering, quality control and research and development areas of the plant. Some of the increase in engineering staffing costs occurred as a result of CSL's decision to retain in-house expertise for repairs and maintenance and reduce its reliance on contractors. The forecast had assumed that this function would be outsourced, with provision to pay contractors included in the repairs and maintenance cost category. DHAC advised ANAO that, accordingly, about $1.2 million or 20 per cent of the increase in labour costs was offset by a corresponding reduction in the repairs and maintenance cost category.

3.65 DHAC further advised ANAO that:

> *The Department accepted all of these* [CSL's arguments] *as being reasonable, given that the plant was not fully operational at the time the forecast estimates were derived and through-puts were low in the first two years . . . The Department did not specifically seek any legal or other expert advice in relation to the increased staff numbers but rather relied on its own assessments within the parameters it had set itself to finalise the review.*

3.66 One of the reasons advanced by CSL for the increase in labour costs was the move, in 1995, to parallel batch processing (involving 24-hour plant operation). DHAC advised ANAO that it accepted that the benefits of parallel batch production, including the resulting increased output, accrued to the processing of foreign plasma as well as domestic production. However, the Department noted that, even if this potential benefit could have been calculated, the terms of reference for the Initial Review stipulated that the allocation of fixed costs between domestic and foreign operations would have been on a 90:10 basis. In this circumstance, the Commonwealth was liable for the majority of any costs in any case.

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[45] The key reasons advanced for the increased staff numbers and costs in the production, quality assurance and research and development areas included:

- forecasts were based on end to end batch processing rather than parallel batch processing which involves concurrent production of two batches of product at any one time. This method was introduced to obtain production capacity and resulted in increased staff numbers and 24-hour plant processing using 12-hour shifts;
- the full impact of complying fully with the code of Good Manufacturing Practice (GMP) requirements under the *Therapeutic Goods Administration Act 1989* was not appreciated in the forecast and increased requirements under TGA regulations on quality control testing and virology requirements; and
- the number of lots of plasma processed per year had increased due to the requirement for smaller batch volumes.

3.67 In November 1999, CSL advised ANAO in response to the section 19 proposed report that:

> *The report findings on increases in labour costs are generally correct. However, they do not emphasise the fact that, while the Independent Expert engaged for the Initial Review was unable to benchmark the labour levels, CSL provided a report from a suitably qualified independent expert. Staffing levels have continued to increase since the Initial Review due to requirements for additional product safety testing in the manufacturing process and increased volume.*

3.68 **Finding:** In Calendar Year 1995, CSL's labour costs were $16.7 million, $5.7 million or some 52 per cent more than the forecast of almost $11 million. Staff numbers were 117 people and 58.5 per cent more than forecast. The Department accepted all of CSL's arguments for the increases in labour costs as reasonable and agreed that the cost structure on which prices were based be adjusted accordingly.

Chromatographic gels

3.69 A third area where there was a significant variation between the forecast and 'actual' costs as determined by the Initial Review was the Fixed Materials cost category. The total variance to the forecast was $3.5 million[46], nearly $1 million of this related to the inclusion in the cost structure of an annual amount for chromatographic gels. The forecast was predicated on the assumption that these gels had a similar useful life to other plant and equipment, that is 10 years. Accordingly, the initial capital cost of the gels ($1.06 million) was included in the plant's asset base for depreciation.

3.70 The Broadmeadows plant was the first plasma fractionation plant of its size in the world to be built using almost exclusively chromatography technology for fractionating plasma. The majority of the industry world-wide remains reliant on the cone ethanol method of fractionation. CSL advised the consultants that the forecast assumption (that the useful life of the chromatographic gels was 10 years) was wrong and that their useful life was one to four years depending on the particular gel. Accordingly, CSL argued that the costs of the gels should be removed from the asset base and that an annual amount should be included the fixed costs category. No costs were actually incurred by CSL for chromatographic gels in Calendar Year 1995.

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[46] From the material available to it from DHAC, ANAO was unable to identify the reasons for the remainder of this increase.

3.71 The consultants summarised CSL's explanation in its report of 10 April 1996 and then put the matter to DHAC and CSL to resolve. The minutes of the 10 April 1996 meeting of the parties with the consultants record that the Department agreed in principle with the inclusion of the costs proposed by CSL but required that the consultants review them in detail and provide calculations supporting the amount. For the 22 April 1996 meeting of the parties with the consultants, CSL had revised the annual amount claimed from some $916 000 to $876 000 and provided details of the calculation of this amount. The amount claimed was calculated by annualising the anticipated future costs less an amount for depreciation of the gels initially included in the asset base.

3.72 In the minutes of the 22 April 1996 meeting, the consultants recorded that they had not had an opportunity to review the new calculation of these costs but

> *the parties have accepted the inclusion of these costs in principle. When* [the consultants] *verify these costs as reasonable, they will be included in the calculation of new schedule prices.*

The costs as proposed by CSL in the 22 April 1996 meeting were subsequently included in the 'actual' cost structure for Calendar Year 1996 but no contemporaneous record was available to ANAO, which indicated that the consultants had verified the reasonableness of these costs and provided a rationale for doing so. In November 1999, the consultants advised ANAO that they did verify the reasonableness of the costs regarding chromatographic gels and verbally advised both parties.

3.73 The DHAC Branch which managed the Department's involvement in the 1996 Initial Review did not seek any expert assistance to inform its negotiations with CSL on this matter. The Department advised ANAO that:

> *CSL sought agreement to remove this item from depreciation and place it in the item for materials. Whilst no replacement costs were actually incurred in 1995, the Department agreed the proposal was reasonable. Given the initial assessment of useful life was incorrect some adjustment was obviously required. It was then and is still a matter of fact that the code of Good Manufacturing Practice requires that gels and resins be replaced more frequently than at 10 year intervals. The decision was also consistent with the Department's negotiation objective to reduce the likelihood of CSL seeking another price review in the future.*

3.74 In November 1999, CSL advised ANAO in response to the section 19 proposed report that:

> *While the cost of gels was not actually incurred in 1995, the parties recognised that gels would be significant operating costs going forward, and accordingly these costs were estimated by the parties for the purposes of the Initial Review. At the time of the commissioning of the facility the "useful" life of Chromatographic gels was poorly defined in the industry and was dependent on ongoing monitoring of the gel performance. Our records show that from July 1996 to October 1999 actual expenditure on gels has totalled $3.4m. This is an average expenditure of $1.0m p.a.*

3.75 **Finding**: DHAC agreed to the removal of chromatographic gels from the asset base and the inclusion of an amount of some $876 000 for these gels into CSL's 1995 Calendar Year cost structure. No replacement cost for chromatographic gels was actually incurred by CSL in 1995 but CSL has advised ANAO that, since July 1996, average expenditure on chromatographic gels has been in the order of $1 million per annum.

4. Product Safety Regulation

This chapter examines Commonwealth product safety regulation of the plasma fractionation.

Regulatory arrangements

4.1 The 1995–96 audit report noted that, while the national blood supply system had seen important technical, regulatory and legislative developments in recent years, it had been the subject of safety and licensing concerns which emphasise the inherent risks in biological products. These risks are illustrated by the large number of hemophiliacs who contracted AIDS before 1984 and Hepatitis C before 1990–91 as a result of blood transfusions, and/or the use of plasma-derived products (prior to the introduction of previously unavailable plasma screening procedures to identify those particular viruses).

4.2 The Therapeutic Goods Administration within DHAC is the Commonwealth entity responsible for the regulation of therapeutic goods including the plasma products produced by CSL. The role of the TGA is to develop and implement appropriate national policies and controls for medicines, medical devices and chemicals.[47] Accordingly, TGA is charged with the responsibility for the regulation of the manufacture of fractionated plasma products including the setting of standards and monitoring of compliance with those standards. Plasma products are classified as therapeutic goods and are subject to TGA product registration requirements. Regulations under the *Therapeutic Goods Act 1989* specify that all plasma-derived products destined for use in Australia be registered on the Australia Register of Therapeutic Goods (ARTG). Products intended for export must meet the requirements of product listing on the ARTG but do not need to be registered.

4.3 The Therapeutic Goods Act prohibits any manufacture of therapeutic goods (including exports) being carried out at premises in Australia unless the manufacturer is licensed to manufacture those goods at its facility. The Therapeutic Goods Act empowers the Minister to determine written manufacturing principles to be observed by manufacturers of therapeutic goods relating to, among other things, standards to be maintained, the procedures to be adopted, and the manufacturing practices to be employed in the manufacture of such goods.

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[47] TGA Corporate Plan 1997/1998 to 1999/2000—Mission Statement.

Under the Act, the Secretary of DHAC is required to grant a license on a valid application unless he or she is satisfied that the applicant will be unable to comply with the manufacturing principles. The licence is granted after payment of an application fee and the completion of an initial audit by the GMP Audit and Licensing Section of the TGA to establish compliance with the requisite Australian Code of Good Manufacturing Practice (GMP).[48]

Code of Good Manufacturing Practice

4.4 The 1995–96 audit reviewed the regulatory arrangements for the production of plasma products for domestic consumption. ANAO found that while the quality assurance undertaken by ARCBS in blood collection for supply to CSL is subject to a specialised TGA Code of Good Manufacturing Practice for Therapeutic Goods (GMP), the GMP used to establish licensing requirements for manufacturers in fractionation of blood plasma products is the GMP—Medicinal Products rather than a specialised GMP for fractionation of blood plasma products.

4.5 ANAO recommended that TGA consider conducting a formal evaluation of the merits of adopting a specialised GMP for fractionation of blood plasma products as part of its overall risk strategy assessment.[49] The Department disagreed with ANAO's recommendation advising as follows:

> *Disagree with the recommended formal evaluation but note that the Department has already sought advice on the suggestion from the Secretariat of the Pharmaceutical Inspection Convention, which is the pre-eminent international body on GMP. The Department's action on this will depend on the advice from this and other expert sources.*

4.6 In the 1995–96 report, ANAO noted the Department's advice that it had sought advice from the Secretariat of Pharmaceutical Inspection Convention (PIC) on GMP but that the recommendation was directed to ensuring that the national interest is fully protected by ensuring that Australia is at the forefront of international good practice in this field.

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[48] TGA standards for regulation of fractionation of blood plasma products are established by a combination of:

- quality standards on plasma set through the British Pharmacopoeia Monograph on Plasma for Fractionation and Individual Products arising from the Fractionation Process;
- the product regulatory process which evaluates the quality, safety and efficacy of products for supply in Australia as a prerequisite for inclusion on the ARTG;
- the GMP which establishes licensing requirements for manufacturers; and
- the TGA post-market surveillance of individual products.

[49] Audit Report No.14 1995-96, *The Sale of CSL—Commonwealth Blood Product Funding and Regulation*, Recommendation No.14 p.58.

4.7 In February 1996, TGA raised the issue of whether or not there was a need for a specialised GMP for fractionation of blood plasma products at the 53rd Meeting of the PIC's Committee of Officials in Geneva. TGA submitted a paper to the Committee Meeting which reported the ANAO's recommendation and sought the PIC's views on whether the existing Guide on GMP provided adequate guidance for manufacturers and regulators regarding the factors to be considered for the manufacturer of products derived from human blood / plasma, or, whether there is a need for a specialised GMP guideline.

4.8 The discussion which followed led the Committee to conclude that:

> *it was agreed that a special guide for fractionation of blood plasma products should not be elaborated but that the Annexe of the present guide should be improved. It was mentioned that the EU* [European Union] *Guide was currently being revised and that the conclusions reached by the Expert Circle in Denmark had been forwarded to the EU Commission.*

4.9 TGA officers also discussed the issue of the ANAO recommendation for a separate GMP for fractionation of blood plasma products with international counterparts in the context of a meeting of the International Society of Blood Transfusion (ISTB) in Japan in March 1996. At this meeting the part played by the European Committee for Propriety Medicinal Products (CPMP) guidelines was raised. The CPMP guidelines are addenda to generic and / or national regulations and are not contained within a code of GMP. These guidelines, which are mandatory within the European Union, are stand alone documents for use by industry and evaluators. At the ISTB meeting TGA was advised that, in Europe, the CPMP guidelines for determining the quality and safety of blood products prepared by fractionation had already been adopted by national control agencies. The CPMP guidelines are primarily used for the pre-market evaluation of product data, but they are also used during GMP inspection of blood fractionation centres to supplement the existing EC or PIC *GMP Guide for the Manufacture of Sterile Medicinal Products.*

4.10 In Australia, CPMP guidelines are usually adopted as a component of the Australian Guidelines for Registration of Drugs. The CPMP guidelines on plasma for fractionation were adopted into the Australian Guidelines for the Registration of Drugs following discussions with CSL. TGA advise that the CPMP guidelines were in use from 13 September 1996 while consultations continued with CSL and were formally adopted in August 1997. The CPMP guidelines specifically address issues such as

the screening and viral inactivation procedures that CSL is required to adopt in the production of individual blood plasma products. TGA approves the Standard Operating Procedure (SOP) that CSL is to apply in the production of each product and monitors CSL's compliance with the approved SOPs through its audit program. In addition, since the 1995–96 ANAO audit, TGA advises that it is increasingly making use of expert advice from within its own pre-market evaluation areas to supplement the expertise of its auditors when conducting GMP audits of CSL.

4.11 In July 1996, the Director of the Conformity Assessment Branch within TGA wrote to the Assistant Secretary Internal Audit Branch regarding ANAO's recommendation advising that TGA had obtained advice from the PIC Secretariat and from a meeting of the ISTB and that following evaluation of this advice, TGA was adopting the following formal policy:

- TGA will continue to adopt a similar approach to that followed by Europe, rather than developing a specific Code of GMP for plasma fractionation centres;
- TGA will continue to adopt appropriate CPMP guidelines, including those which relate to plasma fractionation; and
- TGA will continue to provide comments on draft CPMP guidelines and European Pharmacopoeial Monographs.

4.12 **Finding:** As it reported in its response to Recommendation No.14 of the 1995–96 ANAO audit report, TGA sought advice from peak international bodies regarding the need for a specific Code of Good Manufacturing Practice for plasma fractionation centres. TGA took this advice into consideration in evaluating the merits of, and eventually deciding against, the adoption of a specialised Code of Good Manufacturing Practice for fractionation of blood plasma products.

TGA Good Manufacturing Practice compliance auditing

4.13 TGA conducts audits of CSL's fractionation facility at Broadmeadows to assess whether the requirements under the *Therapeutic Goods Administration Act 1989*, including the *Manufacturing Principles* determined under the Act, for the continued licensing of premises are met. Auditing is a key tool in ensuring compliance with the code of GMP. CSL's ongoing commitment to quality assurance is also assessed by these audits. In conducting audits, TGA officers use the Code of Good Manufacturing Practice for Medicinal Products as a reference, CSL's

SOPs for production of its products, and the CPMP guidelines for products derived from human blood or human plasma.

4.14 The Therapeutic Goods Act and internal TGA protocols determine all aspects of inspections, including methods, notification, length, frequency, reporting and ratings. The final step in the auditing process is the allocation of TGA rating of the facility's level of compliance with GMP for the aspects covered by the audit. Decisions on subsequent re-inspection frequency of each aspect of the facility are based upon this rating.

4.15 Concurrently with the 1995–96 audit of the sale of CSL, ANAO examined TGA's role as a product safety regulator in another audit reported in Audit Report No.12 1995–96 *Risk Management by Commonwealth Consumer Product Safety Regulators*. In this report ANAO recommended[50], in relation to the GMP audit process for all therapeutic goods manufacturers, that TGA adopt a risk based approach to scheduling audit of manufacturers; re-audit manufacturers in accordance with its current re-audit frequency objectives; rate manufacturers as not complying with the manufacturing principles if they are found to have major deficiencies in complying with the code of GMPs; consider making greater use of legislative remedies where non-compliance with the manufacturing principles is detected; and better coordinate its post market regulatory activities which could include the adoption of guidelines facilitating prompt and consistent decision making, with the use of regulator powers where appropriate.[51]

Frequency of audits

4.16 In response to this ANAO recommendation, TGA agreed with the first two points, disagreed with the third and fourth points and agreed in principle with the final point. TGA has reviewed its GMP audit operations in light of the two 1995–96 ANAO audits. TGA's current guidelines, consistent with the recommendations made by ANAO in 1995, state in relation to the frequency of audits that

> *the frequency of audit of manufacturers of therapeutic goods must be based on the degree of risk to patients and consumers in relation to the extent to which a manufacturer complies with GMP and the type of products manufactured, as well as a range of other risk factors.*[52]

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[50] Audit Report No.12 1995–96, *Risk Management by Commonwealth Consumer Product Safety Regulators*, Recommendation No.9.

[51] The ANAO also noted that TGA might also benefit from seeking to develop and implement information systems that facilitate a coordinated regulatory approach.

[52] TGA SOP 303.1 p. 2

4.17 TGA's current guidelines provide that blood collection, separation and testing centers have been assessed as having a 'high' risk rating as do manufacturers of sterile product. CSL's manufacturing activities have therefore been assessed as high risk. The guidelines require that GMP audits of some kind are to be completed every 15 months for such manufacturers, provided they were assessed as acceptably meeting the GMP requirements on their last audit, and every two months for manufactures who have been found to be unacceptable on their last audit[53].

4.18 TGA undertook audits of some or all areas of the operations of the Broadmeadows plant in March 1995, September 1995, November 1995, February 1996, May 1996, December 1996, March 1997, March 1998, May 1998 and March 1999.[54] In this circumstance, TGA has complied with its guidelines in relation to audit frequency. All of these audits were announced audits.

Close out of audits

4.19 ANAO reviewed the audits of the Broadmeadows plant completed by TGA since the sale of CSL. The audit papers indicated that the audits were conducted in accordance with TGA's guidelines. These audit papers document a process whereby the processes and procedures at the Broadmeadows plant were reviewed to ensure they were in accordance with SOPs. The areas of manufacturing, including quality systems, are audited for compliance with the quality assurance system specified in the Manufacturing Principles.

4.20 During each audit, the audit team notes any nonconformities with the required practices and processes. The nature and significance of these nonconformities is determined and an audit report prepared. At an exit interview with the company, the auditors give an oral overview of the audit and its outcome, then review any nonconformities. TGA's procedures require that manufacturers be advised that a response to any audit report is expected within four weeks from the date of the audit[55].

4.21 Before an audit can be formally closed out the manufacturer must address, to TGA's satisfaction, any significant nonconformities with the approved SOP identified in the audit report. TGA's SOP provides that objective evidence of corrective action to address minor nonconformities

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[53] SOP 303.1 p. 5

[54] The November 1995, February 1996 and May 1998 audits were of all areas, the remaining audits examined selected areas.

[55] SOP 401.1 p. 12

is not required for a company to receive an acceptable rating for GMP compliance. Correction action for minor nonconformities is followed up in the context of the next audit.[56]

4.22 The first audit to be conducted after the introduction of the current SOP was undertaken in May 1998. This was an audit of all areas of CSL's operations. A range of significant noncomformities were identified by the audit team and referred to CSL for resolution. TGA continued to exchange correspondence with CSL on some of the nonconformities identified in this audit until December 1998. At that time TGA's Chief GMP Auditor decided that a GMP Auditor should undertake a special visit to CSL to discuss three specific outstanding issues of non-conformance from the May 1998 audit. This was on the basis that they represented sticking points preventing TGA from rating the company as compliant with the code of GMP. On 1 December 1998, the TGA auditor visited CSL and the company agreed to provide a revised corrective action plan to TGA. After consulting TGA further, the company submitted a revised plan in early January 1999. The TGA auditor who undertook the 1 December 1998 visit to CSL recommended to the Lead Auditor and the Chief GMP Auditor that they accept the CSL's proposed actions and timings as adequately addressing the outstanding issues.

4.23 Shortly after submitting the revised plan, CSL requested that TGA issue it a Certificate of GMP Compliance noting that the company's current certificate had expired in December 1998. The Chief GMP Auditor asked the Lead Auditor from the TGA team which had conducted the May 1998 audit for a recommendation on CSL's request. The Lead Auditor advised the Chief GMP Auditor that the

> *CSL Bioplasma license is still active; they have made progress in addressing issues raised; therefore no apparent justification for refusing GMP Certificate.*

TGA advised ANAO that this constituted a decision that CSL's proposed response to the remaining issues from the May 1998 audit were satisfactory and that the audit could be closed out. Accordingly, the Certificate of GMP Compliance requested by CSL was issued on 3 February 1999 and two further certificates were issued on 23 February 1999.

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[56] TGA's SOP further provides that *if a licensed manufacturer obtains an unacceptable rating after objective evidence has been submitted by the company, the matter must be referred to a Review Panel for decision on the most appropriate action to take… If an audit of a licensed manufacturer reveals a situation where consumer safety is likely to be at risk, the lead auditor must convene a Review Panel meeting as soon as possible after the audit for a decision on the most appropriate action(s) to take.*

4.24 The certificates issued to CSL in February 1999 state

> *from the knowledge gained during the last audit conducted on 11–14 May 1998 it is considered that the company complies with the Australian Code of GMP for Medicinal Products which encompasses all recommendations of the World Health Organisation in relation to GMP.*

However, the May 1998 audit was not closed out on TGA's GMP audit database until 12 April 1999, well after the Certificates of GMP Compliance were issued to CSL in February 1999.

4.25 TGA advised ANAO an internal investigation had revealed that, although the Lead Auditor made a decision that a Certificate of GMP Compliance could be issued on the basis of the outcome of the 1 December 1998 visit to CSL, the Lead Auditor did not complete the required post audit file note for the May 1998 audit following the 1 December 1998 visit and the 14 January 1999 decision to approve the issuing of the Certificate of GMP Compliance. Accordingly, the requisite documentation for updating of TGA's audit database was also not completed.

4.26 TGA advised ANAO that, as a result of this internal investigation, its internal procedure for issuing Certificates of GMP Compliance has been amended to make it very clear that these certificates must not be issued unless the audit referred to on the certificate has been closed out on the computer.

4.27 A further scheduled audit of CSL was carried out in March 1999. This audit covered the areas of records, traceability of plasma through the production process, imported plasma, computers, validation of processes and microbiology. The audit report provided to CSL at the audit exit interview detailed three areas of nonconformity with the code of GMP. CSL wrote to TGA on 19 April 1999 providing information on the action it was taking regarding each of these matters. The company's response was acceptable to TGA and the audit closed out on 18 May 1999.

4.28 TGA advised ANAO in September 1999 that:

> *TGA has reviewed its procedures and practices for auditing compliance with the Code of Good Manufacturing practice and taken remedial action to ensure significant nonconformities identified at audit do not remain unresolved for extended periods of time. GMPALS' SOP 401* [the standard operating procedure for TGA GMP auditors] *was revised on 25/1/99 and again on 11/5/99 to clarify issues that are raised in the draft audit report.*
>
> *Changes include the completion of a Post Audit Close Out Form, in which the review and close out of each significant nonconformity is*

required. An audit is considered to have been finalised and closed out only when all nonconformities have been corrected to the satisfaction of the lead auditor. When corrective action of significant nonconformities includes extended timeframe, this must be agreed by the lead auditor. Provided that the audit response details the corrective action that will be taken, such nonconformities may be closed out on condition that they are followed up at appropriate intervals to ensure satisfactory completion.

In addition, a list of outstanding audits that have not been closed out on the TGA audit database are forwarded to all auditors on a monthly basis to ensure timely close out and database update. These procedural changes will ensure that future audits of CSL will be closed out in a reasonable timeframe and not remain unresolved for extended periods of time.

4.29 **Finding**: TGA's May 1998 audit of CSL's Bioplasma Division's compliance with the code of Good Manufacturing Practice (GMP) was not finalised, and the company's compliance with the code of GMP rated acceptable, until January 1999, some eight months after the audit was carried out. TGA's audit database was not updated until mid April 1999 to reflect the decision to finalise the audit.

4.30 TGA issued Certificates of GMP Compliance to CSL in February 1999 that relied on the May 1998 audit as evidence of CSL's compliance with the code of GMP, notwithstanding that the audit was not recorded as finalised in its audit database. TGA has now amended its internal procedure for issuing Certificates of GMP Compliance to make it clear that these certificates must not be issued unless the audit referred to on the certificate has been recorded as finalised in the database.

4.31 TGA's most recent audit of CSL's Bioplasma Division carried out in mid March 1999 was finalised in two months, following the provision of satisfactory responses by the company to nonconformities identified in the audit. TGA advised ANAO in September 1999 that it has reviewed its procedures and practices for auditing compliance with the Code of Good Manufacturing practice and taken remedial action to ensure that significant nonconformities identified during audits do not remain unresolved for extended periods of time.

Notification procedures for incidents relating to domestic plasma

4.32 During field work at TGA in April 1999, ANAO noted that in November 1998 TGA had been made aware of a test kit failure in a batch of screening kits for Hepatitis C Virus (HCV) used by the New South Wales (NSW) ARCBS. TGA's subsequent advice to ANAO was that in October 1998 NSW ARCBS noticed that it was encountering problems with a particular batch of screening kits. By 27 October 1998 it was resolved that the problem was possibly related to a batch failure and that the manufacturer should be contacted. The Director of NSW ARCBS and CSL (as sponsor of the kit and as plasma product fractionator) were informed about the problem on 5 November 1998. NSW ARCBS requested a recall of plasma products. CSL completed manufacture of material containing NSW plasma that was already in the system and this product was quarantined. It subsequently transpired that none of the plasma affected by the test kit failure had been processed by CSL prior to the NSW ARCBS notification of the problem. On 6 November 1998, CSL stopped pooling all plasma from NSW.

4.33 From the documents available to ANAO it appeared that, while the NSW ARCBS had apparently notified CSL of the matter on 5 November 1998, TGA was not notified by NSW ACRBS until 11 November 1998. In July 1999, TGA provided ANAO with a chronology of events for the incident, which indicated that on 13 November 1998, CSL, as sponsor of the relevant therapeutic good, notified TGA by telephone of the problem and formally notified TGA by facsimile on 17 November 1998. ANAO was concerned at the apparent delay in advice being provided to TGA of potentially contaminated plasma being received and processed by CSL.

4.34 In September 1999, TGA advised ANAO that under Clause 820 of the Code of Good Manufacturing Practice for Therapeutic Goods—Blood and Blood Components, the ARCBS is obliged to inform TGA of any test kit failures. Specifically,

> *TGA should be informed of any problem associated with a therapeutic good included on the Australian Register of Therapeutic Goods, which is used during the blood collection, handling and processing procedures.*

4.35 TGA further advised ANAO that:

> *There is an element of interpretation as to what time frame is reasonable in this circumstance. TGA will review this clause and its interpretation. As an outcome, TGA expects there will be an educative process through which GMP auditors clarify for the ARCBS what is a reasonable time frame and what is the appropriate route of reporting such incidents.*

4.36 ANAO was also advised by TGA that CSL did not pool any NSW plasma until the results of confirmatory testing of all of the samples had been received. Retesting of all donations was commissioned by ARCBS. The final outcome was that no donations involved in the test kit failure tested positive for HCV.

Figure 4.1
Chronology of events as seen by CSL

On 5 November 1998 the ARCBS activated a recall of all plasma collected in NSW and ACT after 30 September 1998 on the basis of a higher than expected failure rate of the Ortho Hepatitis C antibody test kit. CSL was notified by the ARCBS by phone on the same day. CSL immediately quarantined all implicated plasma that was not in-process. At the time of the recall some of the implicated plasma was in-process. This was taken through to final product and the final product was quarantined.

Actions taken by CSL and ARCBS-NSW eliminated any risk of product being issued from plasma that may have been screened by a sub-standard test kit. There was no product in the field that was affected. ARCBS-NSW provided CSL with additional information by fax on 6 November 1998.

A meeting was held at CSL on 12 November 1998 between ARCBS representatives and CSL to gain a better understanding of the events reported by ARCBS-NSW and to consider and agree on all necessary actions. CSL informed the TGA by telephone on 13 November 1998 that they had quarantined product and plasma for the reasons detailed above.

On 17 November 1998 CSL informed the TGA, by fax, of the outcomes of the 12 November 1998 meeting at CSL. This included detailed information on quarantined stock and plasma, risk assessments, actions taken and planned and a summary of the current understanding of data derived from ARCBS-NSW. This fax did more that merely "formally notify the TGA" as stated in the ANAO report.

Following the fax of 17 November there were comprehensive discussions held with the TGA in order to resolve all issues.

CSL believes that the processes employed in relation to this example were appropriate and in compliance with Clause 820 of the Code of Good Manufacturing Practice for Therapeutic Goods – Blood and Blood Components.

Source: CSL Limited, 24 November 1999.

4.37 **Finding:** An incident occurred in October/November 1998 in New South Wales involving a failed batch of a screening kit for Hepatitis C Virus (HCV). As a result, inadequately screened plasma was sent to CSL. Retesting of all donations affected by the test kit failure was commissioned by the ARCBS. The final outcome was that no donations involved in the test kit failure tested positive for HCV.

4.38 While ARCBS advised CSL of the matter on 5 November 1998, TGA was not notified by NSW ACRBS until 11 November 1998. In July 1999, TGA provided ANAO with a chronology of events for the incident which indicated that CSL, as sponsor of the relevant therapeutic good, notified TGA of the problem by telephone on 13 November 1998 followed by formal notification to TGA by facsimile on 17 November 1998.

4.39 In September 1999, TGA advised ANAO that under Clause 820 of the Code of Good Manufacturing Practice for Therapeutic Goods—Blood and Blood Components, the ARCBS is obliged to inform TGA of any test kit failures. TGA as sponsor of the relevant therapeutic good is also obliged to notify TGA. ANAO considers that it is important that TGA take steps to educate both ARCBS and CSL as to what constitutes a reasonable timeframe in which to report incidents such as test kit failures to TGA.

Recommendation No.3

4.40 ANAO *recommends* the Therapeutic Goods Administration clarify the reporting arrangements for incidents, such as test kit failures, to ensure that the Australian Red Cross Blood Service simultaneously notifies both CSL, as product sponsor, and the Therapeutic Goods Administration, as product safety regulator.

4.41 **DHAC's response** was that it **agrees** with the recommendation.

Regulation of processing of foreign sourced plasma

4.42 The Broadmeadows plant involves significant excess capacity above that required to process domestic plasma supplies. Accordingly, CSL also processes at the Broadmeadows plant plasma from foreign sources. The finished plasma products are then exported.

4.43 The ANAO recommended in its previous audit[57] that the Department review the system for regulating foreign sourced blood and plasma processing in Australia and advise Ministers on any legislative changes required. The Department responded to the ANAO's recommendation by convening, in February 1996, a meeting of interested parties including representatives from the Australian Red Cross, CSL, the Australian Quarantine and Inspection Service (AQIS) and various areas of the Department such as TGA, the then AIDS and Communicable Diseases Branch and what is now the Acute and Coordinated Care Branch.

4.44 The meeting concluded that there was no need to recommend to Ministers that the legislation be amended provided:

- CSL and the overseas plasma collection agencies, which provide plasma to CSL for processing, agreed to implement contracts consistent with the guidelines provided by the European Committee for Proprietary

[57] Recommendation No.15, Audit Report No.14 1995-96, *Sale of CSL–Commonwealth Blood Product Funding and Regulation.*

Medicinal Products (CPMP) entitled *Contribution to Part II of the Structure of the Dossier for Marketing Authorisation–Control of Starting Materials for the Production of Blood Derivatives, Reference No.III/5272/94*; and

- procedures for ensuring compliance with these requirements were adopted.

4.45 The matter was discussed again in a meeting between the National Manager of TGA and CSL Bioplasma management in September 1996. Following this meeting, TGA wrote to CSL noting that it had been agreed that the current contractual arrangements between CSL and the overseas collection agencies providing plasma to CSL would be amended to ensure consistency with the requirements of relevant CPMP guideline. It was further agreed that amendment of CSL's then existing contracts would be accorded a priority and that overseas plasma would not be accepted for fractionation by CSL after 1 January 1997 unless a revised contract[58] consistent with the CPMP guideline had been established and a copy provided to TGA prior to this date.[59]

4.46 Under this agreement, in December 1996 CSL submitted for TGA review Plasma Master Files (including information relating to the use of plasma as a starting material for the production of plasma products manufactured by CSL) for the five countries with which it then had contracts. Under these contracts, CSL undertakes toll fractionation of plasma supplied by these countries. Plasma provided by volunteer donors in each of these countries is fractionated by CSL into a range of plasma products for a fee and then returned to the relevant national blood service.

4.47 TGA received updates of the Plasma Master Files for the suppliers from these five countries in March 1998 and April 1999. TGA advised ANAO that these arrangements allowed TGA to examine the Plasma Master Files for foreign plasma and to take up with CSL any issues it considered to be critical to the safety of Australian product. TGA advised ANAO that no critical issues were noted for the Plasma Master Files for the original five contract countries.

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[58] TGA advised ANAO that the contracts to which the agreement referred are technical contracts specifying the conditions of plasma quality and transport, which are included in Plasma Master Files as a requirement of the current European CPMP guideline 94/5272.

[59] It was also agreed that the overseas collection centres would be subject to regular audit by CSL, or by the National Control Agency in the country of origin. Copies of these audit reports would be held by CSL Bioplasma and provided to TGA officers on request. Each consignment of imported plasma would be accompanied by a statement from the collection agency certifying that the plasma had been collected in accordance with the requirements of the British Pharmacopoeial monograph entitled *Human Plasma for Fractionation*.

Breaches of the 1996 agreement on pre-conditions for processing of foreign plasma

4.48 Until September 1998, TGA was not aware of foreign plasma from any source other than these five countries being imported by CSL for processing at the Broadmeadows facility. Whilst in the United States on another task, a TGA officer detected that CSL had imported a batch of plasma[60] from a US company, for manufacture into a range of products for export to overseas customers.

4.49 As a result of detecting this breach of the 1996 agreement between CSL and TGA, TGA undertook its first ever unannounced audit/site visit of CSL Bioplasma on 24 November 1998. During the visit it was established that this incident occurred in the third quarter of 1997; the plasma was from commercial US donors; and product manufactured from the batch was exported to two foreign countries. In addition, further breaches of the agreement were detected:

- the manufacture of plasma from an American organisation into products intended for clinical trial in the USA, which occurred around June 1998. TGA advised that at 12 May 1999 it was not aware of the amount of plasma and the products derived from this source[61];
- the manufacture of a further batch of plasma into a range of products[62] over the third quarter of 1998 from the same US company as the first batch had come; and
- the reprocessing of a batch of albumin from another US company into a final product for export.[63]

4.50 No permit is required for the import of plasma into Australia. Under *Quarantine Proclamation 1998,* AQIS doesn't require an import permit for blood and blood products where it is human and where it is for therapeutic use. However, AQIS does require a Quarantine Entry for each shipment of such products and this is entered into AQIS' AIMS database. All consignments are inspected on arrival to ensure that they are tissues of human origin and clearly labelled or accompanied by

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60 TGA advised ANAO that a batch of plasma is usually five to seven tonnes.

61 In July 1999, TGA advised that as a result of the breaches it had detected it had been seeking information on production and export of batches manufactured using plasma from overseas suppliers, in order to match import with export.

62 TGA advised ANAO that these products were only released for export after TGA approval. Exports were made to four countries and further sales from this batch may occur in due course.

63 In July 1999, TGA advised ANAO that there is currently no procedure requiring CSL to advise TGA of the import and reprocessing of plasma products such as this albumin. However, TGA advised that it is currently considering whether it is necessary to extend the Manufacturing Principles to include such products.

supporting documentation. Accordingly, while TGA was unaware until November 1998 that CSL had imported plasma from countries other than the five original contract countries, this information would have been available from AQIS' database.

4.51 As well as seeking information on any breaches of the 1996 agreement, TGA's unannounced audit of 24 November 1998 also investigated the implications of these breaches for the safety of the Australian domestic plasma product supply. Accordingly, the TGA team reviewed the measures used at the Broadmeadows plant to ensure adequate cleaning and sterilisation of all equipment and that overseas and Australian plasma is adequately segregated. The TGA audit team concluded that *CSL's segregation and cleaning procedures are satisfactory and should ensure that there is minimal risk of contamination of Australian product.*

4.52 However, the TGA audit team noted the breaches of the 1996 agreement indicated a need for TGA to formalise its procedures for the receipt and evaluation of Plasma Master Files to ensure that CSL is required to have formal approval before overseas plasma comes into Australia. The TGA audit team also noted that

> *it is clear that while the intent of the current measures is to result in such an outcome, the lack of a formal process has allowed CSL to import and process plasma of a high viral safety risk without the TGA's approval.*

4.53 Subsequently, TGA wrote to CSL on 30 November 1998 noting that it had been established that the company had imported plasma from the USA for use in the manufacture of blood products for commercial supply to other countries and that CSL had failed to notify TGA of this. TGA reminded CSL of the September 1996 agreement between CSL and TGA that the company would provide TGA with Plasma Master Files (as per CPMP Guideline III / 5272 / 94) for any plasma obtained from overseas. TGA advised that it was most concerned about CSL's failure to honour this agreement and notified that, consequently, it intended to take action to introduce legislative changes to require the company to notify TGA of any future importation of foreign plasma. In the meantime, CSL was requested to provide TGA with formal notification of any plasma received from the USA in the past and copies of related Plasma Master Files.

Amendment of the Manufacturing Principles

4.54 On 30 October 1998, following analysis of information collected in earlier field work, ANAO wrote to TGA requesting further advice in the context of following up the recommendation in the 1995–96 ANAO audit report that the system of regulation of foreign sourced plasma processing should be reviewed and Ministers advised of any legislative changes required. On 6 November 1998, TGA wrote to ANAO advising that the TGA officer best placed to provide the advice requested by ANAO was overseas and would not be returning until 16 November 1998. Accordingly, TGA offered to have this officer gather the information on his return and forward it to ANAO during the week of 23 November 1998. ANAO subsequently arranged a meeting with TGA for 30 November 1998.

4.55 At the 30 November 1998 meeting, TGA advised ANAO of its detection of the breaches of the 1996 agreement, the subsequent unannounced audit of CSL on 24 November 1998, and its plans to take action to formalise the requirement that Plasma Master Files be provided to CSL in advance of any import and processing at the Broadmeadows plant of plasma from foreign sources. TGA undertook to advise ANAO of the decision reached on how the requirement to provide Plasma Master Files for approval in advance of any processing at the Broadmeadows plant was to be implemented.

4.56 On 2 December 1998, TGA wrote to CSL advising of the details of proposed changes to the Manufacturing Principles determined under the *Therapeutic Goods Act 1989* in relation to preconditions for the processing of foreign sourced plasma at the Broadmeadows plant. On 3 December 1998, the company sent a facsimile to TGA confirming that it would comply immediately with the intended changes.[64] On the same day, TGA sent a facsimile to ANAO advising of the decision to amend the Manufacturing Principles and providing a copy of the disallowable instrument and explanatory statement. TGA advised ANAO that

> *the plasma master files, when prepared according to CPMP requirements, contain sufficient information for the assessors at TGA to determine if there is risk to Australian product of cross-contamination from the processing of the foreign plasma, taking into account the procedures used at the plant.*

[64] In May 1999, TGA advised ANAO that CSL had submitted complete plasma master files for each of the foreign sources of plasma processed at the Broadmeadows plant.

4.57 From 7 December 1998, the *Therapeutic Goods (Manufacturing Principles)* have provided that:

> *Any blood processing plant:*
>
> *(a) that is used to process plasma collected from donors in Australia; and*
>
> *(b) that processes plasma described in paragraph (a) above for products that are or will be used in Australia ("the Australian product")*
>
> *Shall not be used to process any plasma collected from any source outside of Australia ("the foreign source") unless, in relation to that particular source:*
>
> *(c) a plasma master file, prepared in accordance with the requirements of the Committee for Proprietary Medicinal Products Guidelines entitled "Contribution to Part II of the Dossier for the Application of Marketing authorisation—Control of Starting Materials for the Production of Blood Derivatives (reference CPMP III/5272/ 94)" has been submitted to the Secretary by the licensee of the relevant blood processing plant; and*
>
> *(d) the Secretary has advised the licensee of that plant, based upon the plasma master file referred to in paragraph(c) above and having taken into account the plant's processes, that the plasma from the foreign source will not contaminate the Australian product with any blood borne pathogens.*

4.58 On 25 May 1999, ANAO wrote to TGA seeking confirmation that the Secretary or his delegate had, pursuant to subsection 5(9)(d) of the *Therapeutic Goods (Manufacturing Principles)*, advised CSL, in respect of each of the plasma master files for foreign sourced plasma processed at CSL's facility since 7 December 1998 that, based upon the plasma master files and having taken into account the plant's processes, the plasma from the foreign source will not contaminate the Australian product with any blood borne pathogens.

4.59 In July 1999, the Department advised ANAO that:

> *up until the time of your letter (25 May 1999), the Secretary or his delegate had not made approvals pursuant to paragraph 9(d) of the Manufacturing Principles. Subsequently, the Delegate of the Secretary approved plasma master files for* [four of the five original contract countries] *on 10 June 1999.*[65]

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[65] TGA further advised ANAO that negotiations regarding plasma master file for the fifth original contract country are ongoing and CSL has been informed that no authority to fractionate plasma from this country will be forthcoming until the issues are resolved.

4.60 AGS advised ANAO in July 1999 that, after 7 December 1998, processing of plasma from a foreign source at the Broadmeadows facility, in the absence of advice under section 5(9)(d) of the Manufacturing Principles from the Secretary or his delegate, breached the requirements of this section of the Manufacturing Principles. TGA advised ANAO that no critical issues were noted for the plasma master files from the five original contract countries. TGA initially satisfied itself with respect to risk of transferring blood borne pathogens to the Australian product. However, the plasma master files were still under evaluation at the time of the change in the Manufacturing Principles, since there were still some minor technical issues outstanding. TGA advised ANAO that

> *When the Manufacturing Principles were introduced on 7 December 1998, it was not intended as a means of preventing fractionation of plasma from these five countries, covered under the previous arrangement and from which no critical issues had been identified.*

Independent Review requested by the Minister for Health and Aged Care

4.61 In May 1999, the Minister for Health and Aged Care requested an independent expert to undertake an inquiry into the breaches of the 1996 agreement. The Minister requested a report on the incident and any consequent safety implications by 15 June 1999.[66]

4.62 The independent expert's report submitted on 11 June 1999 advised that the failure to submit appropriate details to TGA regarding several lots of foreign plasma was acknowledged by CSL and that it was due to a changeover in key regulatory affairs staff in July 1997, where the new staff members were not aware of the then existing TGA requirements in regard to imported plasma. The report noted that the upgraded and strengthened requirements of TGA in regard to foreign plasma are now well understood by CSL, and a similar oversight is not likely to occur in the future. The report stated that

> *As far as any consequent potential risk to public health and safety is concerned, the measures in place at the time and subsequently have ensured that there was no increase in the already minimal risk to the Australian community through its blood and plasma product supply. These safety measures included the US Food and Drug Administration*

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[66] The terms of reference for the inquiry required the inquirer to examine all relevant documents associated with the incident and conduct such interviews as necessary to determine: the sequence of events in relation to the incident and ascertain, if possible, why relevant procedures and protocols were not adhered to; and the extent of viral and other risks to public health and safety (if any) that might have arisen as a result of the actions by CSL Ltd.

licensure of the US plasma sources, the protocols in place at CSL for isolation (quarantine) and pre-process testing of the imported plasma and the application by CSL of the same viral safety measures to overseas plasma as apply to domestic plasma.

In summary, CSL acknowledged a failure to meet the regulatory requirements of TGA for foreign plasma which is considered unlikely to occur again. The standard operating procedures in place at CSL since its commissioning ensured that there was no risk to viral safety arising as a result of processing foreign plasma.

4.63 In relation to the breaches of the 1996 agreement between CSL and TGA on foreign sourced plasma, and the incident involving the failure of a batch of Hepatitis C Virus test kits used by the NSW ARCBS, TGA advised ANAO that *it considers that these events have not had any material adverse impact on the Australian plasma products system.*

4.64 In November 1999, DHAC advised ANAO in response to the section 19 proposed report that

The Department has taken action to address the regulatory issues raised by the ANAO (as noted in the body of the report). The Department's view is that the ANAO findings support the Department's overall view that there is a fundamentally safe regulatory system governing blood fractionation in Australia.

4.65 **Finding**: ANAO recommended in Audit Report No.14 1995–96, that the Department review the system for regulating foreign sourced blood and plasma processing in Australia and advise Ministers on any legislative changes required. Consequently, the Department convened a meeting in February 1996 of interested parties. The meeting concluded that that there was no need to recommend to Ministers that the legislation be amended, provided that:

- CSL and the overseas plasma collection agencies, which provide plasma to CSL for processing, agreed to implement contracts consistent with the guidelines provided by the European Committee for Proprietary Medicinal Products (CPMP) entitled *Contribution to Part II of the Structure of the Dossier for Marketing Authorisation – Control of Starting Materials for the Production of Blood Derivatives, Reference No.III/5272/94*; and
- procedures for ensuring compliance with these requirements were adopted.

4.66 In September 1996, TGA and CSL reached an agreement whereby the company would provide TGA with Plasma Master Files (as per CPMP Guideline III/5272/94) for any plasma obtained from overseas. In

October 1998, TGA detected that CSL had breached this agreement by importing and processing plasma from at least one US source without TGA's knowledge and without submitting, in advance, the plasma master file for this source to TGA.

4.67 As consequence, on 24 November 1998 TGA undertook its first ever unannounced audit of CSL's Broadmeadows facility during which confirmation of breaches of the 1996 agreement was obtained. During this audit, TGA also reaffirmed that it was satisfied that CSL's segregation and cleaning procedures are satisfactory and should ensure that there is minimal risk of contamination of Australian product.

4.68 Following identification of CSL's breaches of their 1996 agreement, TGA moved quickly to amend the *Therapeutic Goods (Manufacturing Principles)*. As a result, from 7 December 1998, any Australian manufacturer of blood products for domestic consumption is required to submit plasma master files for any foreign source. As well the former may not process any plasma from such a foreign source until advised by the Secretary or his delegate that, based upon the plasma master files and having taken into account the plant's processes, the plasma from the foreign source will not contaminate the Australian product with any blood borne pathogens.

4.69 TGA advised ANAO in May 1999 that CSL had submitted plasma master files for each of the foreign sources of plasma processed at the Brodmeadows plant. However, between 7 December 1998, and 10 June 1999, with TGA's concurrence, CSL continued to process plasma from four foreign countries without having been advised in accordance with the revised requirements of the Manufacturing Principles. On 10 June 1999, the Secretary's delegate wrote to CSL providing the requisite advice for plasma from these four countries.

4.70 In May 1999, the Minister for Health and Aged Care commissioned an independent inquiry into the incident of the processing of foreign plasma at CSL's Broadmeadows plant without TGA's regulatory requirements having been met. The independent expert's report advised that CSL acknowledged it had failed to meet the regulatory requirements of TGA for foreign plasma but that the standard operating procedures in place at CSL since its commissioning ensured that there was no risk to viral safety arising as a result of processing foreign plasma.

4.71 In relation to the breaches of the 1996 agreement between CSL and TGA on foreign sourced plasma, and the incident involving the failure of a batch of Hepatitis C Virus test kits used by the NSW ARCBS, TGA advised ANAO that *it considers that these events have not had any material adverse impact on the Australian plasma products system.*

4.72 TGA advised ANAO in September 1999 that it has incorporated the need for regular unannounced audits of CSL in its audit scheduling program. ANAO suports this initiative to improve TGA's strategic planning of its auditing of CSL's compliance with regulatory arrangements.

Canberra ACT
22 December 1999

P. J. Barrett
Auditor-General

Appendix

Appendix 1

CSL and Department of Health and Aged Care Comments

Set out below are extracts from the responses provided by CSL and the DHAC to the section 19 proposed report.

Negotiated Outcome

(A) CSL comments

The understanding with the Department was that the PFA would set initial prices for the first 2.5 years. These prices would be adjusted (where necessary) at the Initial Review, with the objective of CSL receiving fair prices for the remaining eight years.

CSL had two major concerns with the PFA concluded with the Commonwealth in 1993.

- *There would be cost relief from upward movements in the Australian Manufacturing Price Index (MPI). CSL is only entitled to price increases on this basis if the MPI increases by at least 1% in 12 months, and this has only occurred once in 1995, despite increases in manufacturing costs at the Broadmeadows plant. For example, labour costs have increased on average 4% p.a. as a result of Enterprise Agreements.*
- *The Initial Review was only a cost review with no scope for any margin increases. In addition, there was a severe limitation on recovering any major cost increases. The PFA provided that CSL would only receive 50% of any additional domestic costs claimed – and only keep 50% of any savings.*

Both concerns have been realised. In the circumstances of the Initial Review, CSL's allowed costs for the 1995 year were some $77.7m compared with the forecast made in 1993 of $66.2m. Consequently, CSL was allowed price increases representing $5.5m and had to absorb the balance of $6m p.a. This effect is substantial over the remaining eight years of the PFA.

It should also be recorded that as a result of the Initial Review, CSL received a price increase of 4.35%. This means that under the PFA, CSL is required to hold its prices constant for current products from June 1996 to 2004 (and possibly 2009) subject only to the possibility of MPI increases. We wonder how many other advanced manufacturers will be able to hold prices constant for this period.

Finally, we are pleased that you have included in the report a table [Figure 3.1] comparing Australian plasma prices with the European market. The table demonstrates that CSL's prices are on average some 75% of European prices in *1999. We consider that this table demonstrates that the Commonwealth is receiving excellent value for the plasma products manufactured by CSL.*

Depreciation

(B) CSL comments

As we have already stated, the Initial Review was structured to set prices for the next eight years based on a number of special purpose provisions included in Schedule B of the PFA, and on [the] cost model [prepared by the adviser who prepared the forecast]. In other words, the cost models developed by [the adviser] were to be adjusted either by reference to: actual costs incurred during the 1995 year; or special purpose provisions in the PFA.

In the case of depreciation, the PFA was explicit on the write-off period to be used, namely 8.5 years, but was not explicit on whether this was to be applied to the historical cost or written down value of the assets at December 1995. Whilst we acknowledge that the wording of the relevant clause in Schedule B was open to interpretation, we consider it is clear that the PFA contemplates a different model from that used by [the adviser] and that the 8.5 year depreciation was to be applied to historical cost. The Department also agreed that this was the intention.

The reasons why depreciation was given this special treatment in the Initial Review were as follows:

i. Whilst the drafting of the PFA in relation to the depreciation issue was not entirely clear, the use of historical cost was not precluded by the wording of the PFA. In our view, this treatment was indicated by the use of the words 'straight line', which in generally accepted accounting principles is used in conjunction with historical cost.

ii. CSL is required to provide state of the art plasma products, equal to the world's best. This requires continued capital investment in the plant to maintain the products at that level. The operation of a high technology plant also requires new equipment to be added from time to time.

iii. It was also expected that the plant would require further capital investment to meet the increase in domestic demand for the plasma products. Domestic plasma intake into the plant has increased from 160 tonnes in 1994 to 232 tonnes in 1999.

iv. Our actual and forecast capital investment for the plant for domestic production from July 1996 is as follows: July 1996 to September 1999 Actual $35.9m; and October 1999 to June 2004 Forecast $37.9m. If these assets were also depreciated on a consistent basis, an additional depreciation charge in excess of $36m would have been required over the eight year period to 2004. In effect, the higher depreciation charges resulting from the use of historical cost were intended to compensate CSL for its inability to charge for straight line depreciation on the same basis for this anticipated future capital expenditure over the life of the PFA. The use of the written down value method would have precluded CSL from recovering these charges.

The use of this historical cost model in the PFA was the principal reason behind the difference between the original forecast cost of $19.8m and the final amount claimed of $29m. We also note that after consideration of all factors surrounding the PFA, including a review of the underlying intentions by both parties, the Department and CSL concurred with the approach adopted.

We have already outlined the circumstances relating to the PFA and the Initial Review interpretation. We consider that the above demonstrates the spirit of the process which lies at the heart of the Initial Review and its special purpose clauses included in Schedule B.

On the basis of the above, we refute totally the allegation that CSL will receive a double payment from the Department over the term of the PFA, due to the use of the historical cost convention. We have demonstrated above that the $17.8m in question was not double claimed and that the interpretation of the Schedule B depreciation clause was "in hindsight" a very accurate way of forecasting what actually is occurring.

Unfortunately for CSL, we only recovered 50% of our depreciation claim (some $4.1m p.a.), which over the remaining life of the PFA amounts to some $32.8m. In our view the reverse of the ANAO's statement is true—the Department benefited to this extent.

(C) Department of Health and Aged Care Comments

The Department's view in relation to the conduct of the initial pricing review under the PFA is that a reasonable outcome was obtained in the circumstances. Given the nature of the pricing structure and the number of factors to be taken into account, the Department believes that the consideration of individual elements, such as depreciation, within this framework should have regard to the overall outcome of the initial review.

In this context, the Department has an alternative view to that contained in paragraph 19 of the Summary of the proposed report. The Department considers that the PFA is ambiguous and uncertain with respect to the approach to depreciation, and that the approach taken by the parties to the contract was one reasonably open to them under the PFA. This view is supported by expert legal advice obtained by the Department.

The Department took a conscious decision on the depreciation issue, which was consistent with the overall approach of reaching a favourable outcome for the Commonwealth. In doing so the Department considered that the aim of the review was to establish new and reasonable prices (having regard to the Commonwealth's overall health objectives and CSL's commercial requirements), and not to put in place a regime that keyed primarily off costs.

The Department does not believe that attributable cost increases were double counted by the Commonwealth over the term of the PFA. This view is supported by expert

accounting advice provided to the Department on this issue. The legal and accounting advice noted above will be forwarded to the ANAO.

The Department notes that the formula contained in the PFA provided for 90 per cent of 50 per cent of the variation between the forecast and actual depreciation expense to flow into prices. The Department also notes that intention from Clause 4(d) of Schedule B to the PFA was to reduce the value of assets owned at 31 December 1995 to zero by 30 June 2004. The Department's interpretation is that 90 per cent of the full value of assets was to be expensed in domestic prices over the life of the agreement.

In this regard, the Department notes that the total amount of depreciation that will be expensed into domestic prices over the life of the agreement under the approach used in the price review (including the depreciation already expensed in the period before the review came into effect) is $219 million.

When compared to the proportion of the asset base to be expensed in the pricing model under the agreement (that is 90 per cent of $246.2 million = $221.6 million), and having regard to:

- *other factors apart from depreciation influencing the pricing model;*
- *the product prices actually paid over the life of the agreement; and*
- *the straight line depreciation of assets to zero by the year 2004;*

the Department believes that there is no "double-counting" of the depreciation factor.

An additional issue that we believe supports the Department's consideration of the reasonableness of the overall outcome in this regard is that we understand that since the Initial Pricing Review, CSL's investment in assets for the Broadmeadows plant has significantly exceeded the forecast levels, for which they obtain no additional depreciation expense through the pricing model.

DHAC asked its legal adviser in November 1999, in the conduct of an Initial Review under clause 3.4 of the PFA, how should clause 4(d) of Schedule B relating to depreciation have been applied? DHAC's legal adviser advised that In agreeing not to use written down value the parties behaved in a manner which was consistent with the contract and its apparent intention. The parties' agreement to use historical cost was an avenue reasonably open to them in the circumstances.[67]

The different approaches to the depreciation issue (that is that taken by the Department and that suggested by the ANAO) result in different financial impacts on the pricing model. The fact that the Department consciously considered the options and chose a particular decision does not give rise to double-counting. Rather, it resulted in higher prices being paid to CSL, a situation foreseen and accepted by the Department.

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[67] DHAC"s legal adviser further advised DHAC in November 1999 that: *The following steps were required*: ***1****. identify the assets owned by CSL on 31 December 1995;* ***2.*** *ascertain the value of those assets;* ***3****. assume that those assets will be depreciated on a straight line basis from 1 January 1996 until 30 June 2004 such that their value at 30 June 2004 will be zero;* ***4****. calculate the annual depreciation amount based on this assumption;* ***5.*** *and use this amount as the actual depreciation cost for 1995. In relation to step two the PFA is unclear and ambiguous on the issue of what value should be applied. It was reasonably open to the parties to reach agreement on the value of assets to be used and use of historical cost was reasonable in the circumstances. In our view, use of the written down value of assets was not intended by the PFA.*

Faced with an unclear and ambiguous provision in the contract, it was open to the parties to agree on a value to be applied for the purposes of calculating depreciation under clause 4(d). We note in this respect that ANAO have criticised the Department for negotiating with CSL to resolve various matters during the conduct of the initial review rather than treating the review as an arbitration as envisaged by the PFA. We note that the Department received advice from [another legal adviser] in relation to this issue and we have been given the opportunity to consider this advice. In our view, that advice correctly indicates that it was open to the parties to resolve any contractual ambiguities by agreement.

The ANAO argues that in agreeing to use historical cost as the starting value for calculating depreciation the Commonwealth has 'double paid' depreciation costs over the first two years of the PFA. This is an argument which would be open if the contract clearly required the use of written down value in calculating depreciation. The approach taken by the parties is in our view clearly sustainable. It is consistent with the PFA as a whole. As outlined above, the PFA restricts CSL in respect of its ability to raise capital by borrowing money and requires CSL to maintain in good order, condition and repair all assets, plant and equipment used for fractionation yet makes no specific provision for recovery of capital expenditure or depreciation on assets acquired after 31 December 1995.

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