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Audit Report No. 24, 1999-2000

Commonwealth Management and Regulation of Plasma Fractionation

Department of Health and Aged Care

Introduction

4.1 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.[1]

4.2 In May 1994, the Commonwealth sold the Commonwealth Serum Laboratories (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 the Australian Red Cross Blood Service (ARCBS). 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.[2]

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1 *Audit Report No. 24, 1999-2000*, p. 11.

2 *Audit Report No. 24, 1999-2000*, p. 11.

4.3 The ANAO audit objectives were to:

- assess the administrative and financial effectiveness of DHAC's contract management of the PFA;
- assess whether the TGA's implementation of post sale regulatory arrangements adequately protected the community's interests, and
- assess the extent to which agencies 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.[3]

4.4 In *Audit Report No. 24, 1999-2000*, the ANAO found that there was significant scope for improvement in DHAC's contract management practices in relation to the PFA, and that the TGA's regulation of plasma fractionation could be improved by giving greater emphasis to ensuring timely resolution of significant nonconformities with the regulatory requirements under the *Therapeutic Goods Administration Act 1989*.[4]

4.5 The ANAO made three recommendations for improving DHAC's contract management of the PFA and implementation of plasma fractionation regulatory arrangements.[5] DHAC agreed to all the recommendations.

4.6 At its hearing on 16 May 2000, the Committee took evidence from DHAC and the ANAO on the following issues:

- payment control;
- product safety regulation, and
- Initial Plasma Fractionation Agreement review.

Payment control

4.7 The audit report found that there had 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

3 *Audit Report No. 24, 1999-2000*, p. 12.
4 *Audit Report No. 24, 1999-2000*, p. 12.
5 *Audit Report No. 24, 1999-2000*, p. 13.

> invoiced for had actually been received by the designated recipients.[6]

4.8 The Committee noted the ANAO findings and asked DHAC what control systems it was putting in place to resolve the deficiency highlighted by the ANAO.

4.9 DHAC stated that, with the assistance of the Australian National University (ANU), it was now developing a system that would fully reconcile all of the goods received by the Red Cross and that it would sample the receipt of goods and products by the non-Red Cross group.[7]

4.10 The Committee noted that a 1995 audit report on the sale of CSL[8] had made the same finding about the lack of an internal control system which could reconcile invoices provided by CSL with the receipt of products. The Committee sought from DHAC the reason it had taken so long to remedy a clear breach of financial accountability.

4.11 DHAC responded that while there was no doubt the department should have moved more quickly than it did to put systems in place to reconcile the invoices, the risk factor was considered to be fairly low:

> Secondly, we kept on holding off developing a reconciliation system because of the expectation that the Red Cross was going to develop a system which would enable that to be done pretty efficiently. In the event, that has taken the Red Cross … a lot longer to do. I think our attention has been sharpened by the ANAO's finding that we had to do something very quickly, especially for those [20 per cent of] payments which were not to the Red Cross …[9]

4.12 DHAC advised the Committee that it was not aware that any money had gone astray and that the matter was now being attended to in a comprehensive manner:

> I think the mechanisms that we have put in place can guarantee your committee looking into the future.[10]

4.13 Responding to the Committee's request for comment on the degree of risk of mis-payment or fraud, the ANAO stated:

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6 *Audit Report No. 24, 1999-2000*, p. 42.
7 *Transcript, 16 May 2000*, p. 20.
8 *Audit Report No. 14, 1995-96*, p. 53.
9 *Transcript, 16 May 2000*, p. 20.
10 *Transcript, 16 May 2000*, pp. 20-1.

> I think the issue is perhaps more fundamental. It is fairly common practice to ensure the receipt of goods before you actually shell out the money. I think it is a fundamental control matter we are talking about, and the control is designed to protect the Commonwealth's funds.[11]

4.14 DHAC agreed that 'notwithstanding the difficulty in implementing a payment control system, the Department should have established a system by the time the second Auditor-General's review took place'.

Committee comments

4.15 It is fundamental that agencies have in place appropriate means to check whether goods have been received prior to payment. The Committee is pleased that DHAC has now implemented a comprehensive payment control system.[12]

4.16 The Committee notes that DHAC advised the ANAO in the 1995-96 audit report that the reconciliation issue was being addressed by the department.[13] Clearly, nothing eventuated. The issue this raises is what assurance the Committee has that ANAO and internal audit recommendations are actually addressed and implemented.

4.17 DHAC has advised the Committee that its internal audit committee is actively pursuing the question of providing assurance that the department acts on recommendations.

4.18 DHAC has assured the Committee that there is a now a line of responsibility for the follow-up and implementation of ANAO recommendations, and that there will be no recurrence of the inertia which followed the earlier recommendation on the payment control system.[14]

Product safety regulation

4.19 In September 1996, TGA and CSL reached an agreement whereby the company would provide TGA with Plasma Master Files for any plasma

11 *Transcript, 16 May 2000*, p. 21.

12 DHAC, Submission No. 1, p. 8.

13 Audit Report No.14, 1995-96, p.53. The Department of Human Services and Health advised the ANAO that 'arrangements are being put in place whereby information on product delivered by CSL to ARCS will be sent to DHSH for each financial year'.

14 *Transcript, 16 May 2000*, p. 22.

obtained from overseas. Under this agreement, CSL provided Plasma Master Files for the five countries with which CSL then had contracts. 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.[15]

4.20 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 from a US company, for manufacture into a range of products for export to overseas customers, without TGA's knowledge and without submitting, in advance, the Plasma Master File for this source to TGA.[16]

4.21 At the public hearing, DHAC stated that CSL's failure to obtain prior approval from TGA before importing and fractionating plasma had not compromised safety:

> Those areas of program administration that needed to be improved were acted on decisively and they were improved, but those particular areas in no way compromised the safety of our blood supply.[17]

4.22 DHAC stated that the situation highlighted the effectiveness of the TGA regulatory system in ensuring the safety of the Australian plasma product supply in that:

- it was a TGA officer who detected that CSL were processing plasma from the United States;
- TGA acted quickly on the information, conducting an unannounced audit of CSL which confirmed other breaches of its 1996 agreement; and
- all foreign plasma was confirmed as exported, and CSL's segregation and cleaning procedures met TGA requirements which eliminated the risk of contamination of Australian product by the overseas sourced plasma.[18]

4.23 The TGA audit team noted 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:

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15 *Audit Report No. 24, 1999-2000*, p. 80.

16 *Audit Report No. 24, 1999-2000*, pp. 81, 87.

17 *Transcript, 16 May 2000*, p. 19.

18 DHAC, Submission No. 1, p. 11.

> It is clear that while the intent of the current measures is to result in such an outcome, the lack of a formal process had allowed CSL to import and process plasma of a high viral safety risk without the TGA's approval.[19]

Committee comments

4.24 The Committee does not agree with DHAC that the discovery and follow-up of breaches in any way highlights the effectiveness of TGA's regulatory system. The Committee notes that the TGA officer who detected the breach of the 1996 agreement between CSL and TGA was in the US on another task and that the breach was a chance discovery.

4.25 The Committee is also aware that the audit carried out at CSL as a result of the breach being detected, was in fact the only unannounced audit which had been conducted by TGA. This audit detected several other breaches of the agreement.[20]

4.26 Despite assurance from DHAC that there was no risk of contamination of the Australian product by the overseas sourced plasma, the Committee remains concerned that the plasma was from high risk commercial US donors and that the product manufactured from the US plasma was exported to two other foreign countries.[21]

4.27 Plasma Master Files contain information which allows the assessors at TGA to determine whether there is risk to Australian product of cross-contamination from the processing of foreign plasma, taking into account the procedures used at the processing plant.[22]

4.28 It would clearly have to be considered an increased risk factor for CSL to be processing plasma of a high viral safety risk, regardless of the level of TGA's confidence in CSL's segregation and cleaning procedures.

4.29 Plasma fractionation is an area which requires an active regulator and a high level of vigilance, characteristics which were not well illustrated in the ANAO's report.

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19 *Audit Report No. 24, 1999-2000*, p. 82.
20 *Audit Report No. 24, 1999-2000*, p. 81.
21 *Audit Report No. 24, 1999-2000*, p. 81.
22 *Audit Report No. 24, 1999-2000*, p. 83.

Recommendation 6

4.30 **The Committee recommends that the Department of Health and Aged Care's Audit Committee conduct regular internal audits of the Therapeutic Goods Administration's performance, and provide to the Committee by December 2001 an updated status report of the effectiveness of the Therapeutic Goods Administration's implementation of its auditing program of Commonwealth Serum Laboratories' compliance with the Code of Good Manufacturing Practice, including the extent to which the Therapeutic Goods Administration is complying with its own procedures and practices for undertaking these audits.**

Recommendation 7

4.31 **The Committee recommends that Commonwealth Serum Laboratories be required on a regular basis to provide positive declarations to the Therapeutic Goods Administration regarding the volume, source and final destination of all foreign plasma imported into Australia by the company and processed at its Broadmeadows fractionation plant.**

Recommendation 8

4.32 **The Committee recommends that agencies implement administrative arrangements to ensure that the Therapeutic Goods Administration is notified of all Quarantine Entries made by the Australian Quarantine Inspection Service of human blood and blood products imported into Australia.**

Initial Plasma Fractionation Agreement review

4.33 At the time that the Plasma Fractionation Agreement (PFA) was negotiated and signed in 1993, CSL's Broadmeadows 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 to the Broadmeadows facility.

4.34 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 ANAO stated in its report that, 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.[23]

4.35 Moreover, the consultants engaged did not commence work until March 1996 and had a reporting deadline of 30 April 1996:

> In this circumstance, the time available to address the extremely complex issues that arose in the course of the review was severely constrained.[24]

4.36 The audit report also noted that DHAC failed to execute a written contract with the consultants who undertook the Initial Review.

4.37 At the hearing, DHAC acknowledged that there was no doubt that it could have implemented a better process in reviewing the PFA. DHAC agreed that the Initial Review was more complex than originally envisaged by the parties or by the drafter of the PFA.[25]

4.38 Nevertheless, DHAC defended the timeframe for the review:

> Despite the problems encountered during the review, the Department considers that the time allowed for the review was sufficient for achieving a reasonable outcome. ….

23 *Audit Report No. 24, 1999-2000*, p. 14.

24 *Audit Report No. 24, 1999-2000*, p. 14.

25 *Transcript, 16 May 2000*, p. 19; DHAC, Submission No. 5, p. 3.

> The Department maintains that [complex issues such as depreciation or chromatographic gels] were dealt with satisfactorily.[26]

4.39 The ANAO received legal advice from the Australian Government Solicitor (AGS) that the process adopted by the consultant, CSL and DHAC was in the nature of a mediation rather than an arbitration and that this represented a significant departure from the terms of the PFA. It also altered the Commonwealth's risk profile in relation to the 1996 Review. AGS further advised the ANAO that the Final Report provided by the consultant on 30 April 1996 did not satisfy the requirements of the PFA, including in regard to proving 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.[27]

4.40 The consultants advised the ANAO in November 1999 that they considered 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. The consultants did not dispute the AGS' opinion that the review was not performed in accordance with the provisions of the PFA.[28]

4.41 The Committee sought information from DHAC on why the review process was not undertaken in accordance with the requirements stipulated in the PFA.

4.42 DHAC responded that at the commencement of the review, it expected the independent expert would arbitrate as outlined in the terms of reference for the review. When it became clear this would not be possible, DHAC agreed to negotiate with CSL to attempt to resolve the difficulties. During the course of the ANAO audit, DHAC received independent legal advice that, as the contract was ambiguous, it was open to the parties to resolve any contractual ambiguities by agreement and not by arbitration.[29]

4.43 In response to the Committee's seeking to know why DHAC had obtained no legal accounting or professional industry expert advice, DHAC stated:

> Had the review gone as planned, the independent expert would have provided the requisite expertise. The Department, therefore, made no plans to engage its own experts, prior to the review

26 DHAC, Submission No. 5, p. 3.
27 *Audit Report No. 24, 1999-2000*, p. 40-50.
28 *Audit Report No. 24, 1999-2000*, p. 50.
29 DHAC, Submission No. 5, p. 3.

> commencing. The department accepts that specialist advice might have provided better assurance and certainty in the negotiation process, once it became clear that the original arbitration process was not going to be fully realised.[30]

4.44 The Committee asked DHAC on what basis it could consider the outcome on CSL's claims for increased costs as reasonable. DHAC replied that the average increase in prices represented the mid-point of the range of potential negotiable outcomes:

> Had the Department accepted all of CSL's propositions on the range of issues that were the subject of negotiation, prices would have increased by 7.4%. Alternatively, had none of CSL's propositions prevailed, prices would have declined by 1.8%.[31]

4.45 DHAC considered that an outcome in the middle of the range of outcomes was reasonable because:

- it was achieved during a period when the increase in Commonwealth outlays for health care was estimated at 6 per cent;
- CSL's revenue per litre of plasma is still significantly less than a selected group of European countries …; and
- the policy objectives of a stable price regime and appropriate economic incentives for CSL were met.[32]

4.46 With the review of the PFA extension in sight, the Committee sought assurance that early planning for it had commenced.

4.47 DHAC stated that increased resources had been put into the relevant area of the Department to attend to both matters raised by the ANAO and to the forthcoming review:

> The Department has recently taken steps to ensure it provides adequate resources for:
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> - managing the CSL contract;
> - planning and policy setting for the Australian blood sector as a whole;
> - positioning itself for future negotiations with CSL; and
> - dealing with the consequences of the National Blood Review.[33]

4.48 DHAC advised that in February 2000 a Taskforce was established in the department under an SES officer with additional resources, including

30 DHAC, Submission No. 5, p. 3.
31 DHAC, Submission No. 5, p. 7.
32 DHAC, Submission No. 5, p. 7.
33 DHAC, Submission No. 1, p. 12.

external consultants. It will be supplemented by further resources following the completion of the National Blood Review in July 2000.

Committee comments

4.49 The PFA is one of the largest long-term contracts the Commonwealth has outside the defence area.

4.50 The Committee finds it difficult to share DHAC's satisfaction with its achievement of agreed cost increases at the mid-point of the range of potential outcomes. It is noted that the outcome was the second highest outcome of the options identified by the Department in its *Comparison of possible costing outcomes* table.[34] The Committee would have had more confidence in the rejection or acceptance of a claim if it had been based on the expert evidence intended to be provided under the review. It would also have had a basis for accepting DHAC's arguments if evidence in the form of written reasons for accepting claims had been documented.

4.51 While the Committee acknowledges that the PFA contract may have had shortcomings, the lack of appreciation of the size and complexity of the process to be undertaken is unparalleled. While it is not unusual for the parties to contracts to resolve ambiguities by agreement, it is crucial that the Commonwealth have available appropriate expert advice to inform significant financial negotiations. Without the benefit of any legal, accounting or expert assistance to inform its negotiations with CSL, the Committee considers that the Commonwealth had insufficient information available to it when it entered into the review process.

4.52 On that basis, the Committee contends that it is not possible to ascertain whether the Commonwealth's outcome was poor or indifferent. What the Committee is more certain of, given the underpreparedness of DHAC and the woeful history of contract management generally in the public sector, is that the conditions which might have led to a good outcome for the Commonwealth were not present.

4.53 The Committee was disappointed to observe that the only legal and accounting advice sought by DHAC in relation to the PFA review was obtained to rebut the audit report findings. The Committee could have hoped for the same effort from DHAC in relation to the PFA review process.

34 DHAC, Submission No. 5, p. 11.

4.54 Despite DHAC's defence of its review process, the Committee notes its acknowledgment that the audit report contained 'some useful lessons' to draw upon for the forthcoming review with CSL. In particular, the Committee welcomes DHAC's preparations for the PFA extension review, and that a consultant has been commissioned to undertake a scoping study on the resources and processes the Department requires (including access to a range of expertise) for negotiating the extension option with CSL.[35]

4.55 It is clear to the Committee that DHAC has some distance to go to achieve satisfactory contract management.

Recommendation 9

4.56 **The Committee recommends that the Chief Executive Officer of the Department of Health and Aged Care assess the skill base and training needs of its contract managers, and ensure that appropriate legal and technical advice is readily available to them.**

Recommendation 10

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

Bob Charles
Chairman
11 October 2000

35 DHAC, Submission No. 5, p. 6.