COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

JOINT COMMITTEE OF PUBLIC ACCOUNTS AND AUDIT

(Roundtable)

Reference: Review of Auditor-General's reports, first and second quarters 2004-05

TUESDAY, 5 APRIL 2005

CANBERRA

BY AUTHORITY OF THE PARLIAMENT

INTERNET

The Proof and Official Hansard transcripts of Senate committee hearings, some House of Representatives committee hearings and some joint committee hearings are available on the Internet. Some House of Representatives committees and some joint committees make available only Official Hansard transcripts.

The Internet address is: **http://www.aph.gov.au/hansard**

To search the parliamentary database, go to:
http://parlinfoweb.aph.gov.au

JOINT STATUTORY COMMITTEE ON

PUBLIC ACCOUNTS AND AUDIT

Tuesday, 5 April 2005

Members: Mr Baldwin *(Chair)*, Ms Grierson *(Deputy Chair)*, Senators Hogg, Humphries, Moore, Murray, Scullion and Watson and Mr Broadbent, Ms Burke, Miss Jackie Kelly, Ms King, Dr Laming, Mr Somlyay, Mr Tanner and Mr Ticehurst

Members in attendance: Senators Hogg, Moore and Watson and Mr Baldwin and Ms Grierson

Terms of reference for the inquiry:

To inquire into and report on:

Review of Auditor-General's reports, first and second quarters 2004-05.

WITNESSES

Committee met at 10.31 a.m.

BAYLES, Mr Neil Ross, Chief Finance Officer, Department of Veterans' Affairs

BICKFORD, Ms Sue-Ellen, General Manager, Financial Services Group, Attorney-General's Department

BLACKBURN, Ms Kerry, Division Head, Department of Veterans' Affairs

BOND, Mr Kim, Senior Director, Performance Audit Services Group, Australian National Audit Office

BOYD, Mr Brian Thomas, Executive Director, Performance Audit Services Group, Australian National Audit Office

COCHRANE, Mr Warren John, Group Executive Director, Australian National Audit Office

CULHANE, Mr Michael, Branch Manager, Finance and Banking Branch, Department of Finance and Administration

FILEMAN, Mr Michael Charles, Acting Chief Finance Officer, Aboriginal and Torres Strait Islander Services

HAZELL, Ms Anne, Division Manager, Financial Reporting and Cash Management Division, Department of Finance and Administration

HUTSON, Mr Jonathan, Division Manager, Financial Framework Division, Department of Finance and Administration

KENNEDY, Mr Trevor, Assistant Secretary, Financial Management, Attorney-General's Department

MOODY, Mrs Donna, Chief Finance Officer, Australian Taxation Office

O'NEILL, Mr Patrick John, Team Leader, Department of Immigration and Multicultural and Indigenous Affairs Agency Advice Unit, Department of Finance and Administration

WALSH, Mr Dermot Gerard, National Manager, Defence Service Homes Insurance Scheme, Department of Veterans' Affairs

WATSON, Mr Patrick Gregory, Acting Chief Executive Officer, Aboriginal and Torres Strait Islander Services

CHAIR—I open today's public hearing, which is one in a series of hearings to examine reports tabled by the Auditor-General in the second quarter of the financial year 2004-05. This morning we will be taking evidence on Audit report No. 15 2004-05: *Financial management of special appropriations.* I welcome witnesses from the Australian National Audit Office, the

Department of Finance and Administration, the Australian Taxation Office, the Department of Veterans' Affairs, the Attorney-General's Department and representatives from Aboriginal and Torres Strait Islander Services, who will all provide evidence on Audit report No. 15. I remind witnesses that today's hearing is a legal proceeding of the parliament and warrants the same respect as the proceedings of the House itself. The giving of false or misleading evidence is a serious matter and may be regarded as a contempt of parliament. The evidence given today will be recorded by Hansard and will attract parliamentary privilege. Do any of you have any comments to make on the capacity in which you appear?

Mr Cochrane—I am Acting Deputy Auditor-General.

Ms Hazell—I am chief financial officer, Australia Government Reporting, at the Department of Finance and Administration.

Ms Blackburn—I am the head of the corporate division at the Department of Veterans' Affairs.

CHAIR—We will run today's session using a roundtable format with witnesses from all the agencies appearing together. However, I ask participants to remember that only members of the committee can put questions to witnesses if this hearing is to constitute a formal proceeding of the parliament and attract parliamentary privilege. If other participants wish to raise issues for discussion, I ask them to direct their comments to the committee. It will not be possible for participants to respond directly to each other. Secondly, given the short time available today and the number of departments here, statements and comments by witnesses should be relevant and succinct. Starting with the Attorney-General's Department, would you like to make a brief opening statement on the report to the committee.

Mr Kennedy—The Attorney-General's Department was reported as not having reported correctly a number of special appropriations. The department's view is that it had maintained records of all transactions and that at the time the amounts were reported it believed they had been correctly reported. The department statements for the relevant years were audited by the Australian National Audit Office and were not qualified. The department has taken steps to put in place measures to ensure that incorrect reporting of special appropriations will not recur. That is essentially the department's statement.

CHAIR—Does the Department of Veterans' Affairs have a statement?

Ms Blackburn—We have three brief comments. The ANAO report reported on the use of funds for payments to prisoners of war of the Japanese. We drew down $1.5 million from consolidated revenue under the CJI special appropriation. At the time, we understood that that was appropriately used for departmental expenses, including promoting the availability of the payments, assessing claims and making system changes to expedite those payments. The audit report subsequently took a different view. We have since had discussions with both A-G's and DOFA and an amount of $250,000 has been repaid as the sum total of the amount that was in dispute.

The second point relates to our overdrawn bank accounts. Our head account inadvertently went into debit balance between 27 and 29 December 2002 as a result of a request for a draw-

down on 24 December not being processed until 30 December by DOFA. There was no cost to the Commonwealth because of that inadvertent breach and no breach of our transactional banking arrangements. We now have measures in place to address any future occurrences of that.

On the third point, the nondisclosure of the use of section 39(9) in relation to Defence Service Homes Insurance, there was reporting disclosure in our financial statements under special accounts. But they were not disclosed in the manner required and this has since been rectified in the 2003-04 financial statements.

CHAIR—Does ATSIS wish to make a statement?

Mr Watson—We have no opening statement to make.

CHAIR—Does DOFA wish to make a statement?

Mr Hutson—Firstly, I want to say how much the Department of Finance and Administration looks forward to working with the newly constituted Joint Committee of Public Accounts and Audit over the next few years on many of the issues which the Audit Office have identified as needing some attention. I would also like to draw the committee's attention to our submission, which we provided to the committee prior to today's hearing. Other than that, we look forward to helping the committee with its inquiry today.

CHAIR—Does the ATO have an opening statement?

Mrs Moody—We have no opening statement.

CHAIR—Does the Audit Office have an opening statement?

Mr Cochrane—We have no opening statement. We will let the report talk for itself.

CHAIR—How did I know you were going to say that? Thank you very much for appearing before us today. Our committee has great concerns about departments, which in essence have drafted their own special appropriations legislation, not being able to understand their own legislation or indeed comply with it. I would ask each department to give us a response on that, starting with the Attorney-General's Department.

Mr Kennedy—The department does not have any special appropriations that it has drafted. Our special appropriations are made under existing legislation. Many of our appropriations are actually dormant and not being used, so we are not in that particular position of drafting anything specifically for the department.

CHAIR—Department of Veterans' Affairs?

Mr Bayles—Regarding the issue of POWJs, we were of the view at the time that the legislation did give us the authority to draw down the money, and the problem occurred as a result of the ANAO coming to a different view several years later, after the legislation had been passed by parliament. We did check with the Government Solicitor, and their view was that it was arguable either way but that the better view was that the legislation did not provide the

authority for what we had used the money for. So, at the time the legislation was passed, we thought we had the matter covered and that it was correct legislation.

Another issue that we have been picked up on in the report was related to the debit balance that we went into in December 2002. That was an inadvertence and was not due to legislation not being understood or followed. The other issue was related to DSH. We are now well aware of the responsibilities in fulfilling our requirements there.

CHAIR—ATSIS?

Mr Fileman—The error occurred, or commenced occurring, nine financial years ago. I believe it was a simple human error at that stage, in which the incorrect indexation factor was applied in the first case, and over the course of the next nine years that precedent was followed by successive administrations. So I think it is characterised as a human error which recurred in those category A years. Those category A years are now finished, so there is no ongoing issue about applying that indexation factor.

CHAIR—And DOFA, who probably draft most of these legislative instruments?

Mr Hutson—We do not draft legislative instruments but, in terms of the special appropriation provisions of the legislation, I think your question very much hits the nail on the head. It effectively draws attention to the technical nature of the special appropriation provisions which are drafted in legislation which is frequently, as you point out, the responsibility of the agency concerned, both in the drafting and in the administration. The only thing I would say about that is that it probably highlights the often very technical nature of dealing with these provisions in legislation. The answers we have heard from my right really identify some of the complexities which agencies have faced in dealing with these issues.

CHAIR—Is it the wish of the committee that the submission from the Department of Finance and Administration dated 23 March 2005 be accepted as evidence to the JCPAA sectional committee, review of Auditor-General's reports and authorised publications? There being no objection, it is so ordered. The Australian Taxation Office?

Mrs Moody—The tax office accept that we have not paid enough attention to some of the details, particularly around the reporting of how that money is spent. I suspect that, again, some of that is buried in history. Some of the newer ones deal with the complexity of making one payment to a taxpayer that will contain money that comes from a number of special appropriations. We have not necessarily focused to the extent that we should—and I might say that we have now, and those things have been fixed—on making sure that the reporting of that payment appears in the appropriate places.

CHAIR—I will raise an issue at the moment, and I will read an extract of the Financial Management and Accountability Act orders of 1997, part 2, 'Special responsibilities of Chief Executives'. Under subsection 2.1, which is titled 'Audit Committee', it says:

2.1.2 The functions and responsibilities of an Audit Committee include:

c. the provision of advice to the Chief Executive on action to be taken on matters of concern raised in a report of the internal auditors or in a report of the Auditor-General concerning the Agency …

I ask each department: what have you done in light of the Auditor's report to provide accurate information on the actions you have taken to identify these areas of weakness and report back to your chief executive? More importantly, what actions have been taken to remedy these? I will start with the Attorney-General's Department.

Mr Kennedy—The issues for the department were that we had not reported our expenditures against the correct appropriation. There were three such situations. One of those situations occurred five years ago, one is ongoing and the third occurred at some point in time. With regard to the ongoing issue—reporting the special appropriations with regard to former solicitors-general—an oral report was provided to the department's audit committee. The report explained what action had been taken in order to remedy that particular reporting issue. The action advice was that a separate ledger code had been established and that all expenditures were being reviewed monthly. For this particular special appropriation with regard to former solicitors-general, it is isolated to the two existing payees. No further solicitors-general will be entitled to payment under the Law Officers Act in this particular case. Immediately after the Australian National Audit Office raised the issues with me, I spoke with my division head and with the secretary of the department and identified the issues and the strategies that we would put in place.

CHAIR—The DVA?

Ms Blackburn—The points raised by the ANAO report were immediately looked at by our national audit and fraud control committee. We already had had a number of discussions with the secretary of the department and the Deputy President of the Repatriation Commission about tightening all of our financial procedures. We sought legal advice and immediately commenced discussions with Finance about the quantum of any amount that may have been inappropriately used by the department and, as I mentioned earlier, we have since repaid $250,000 of the $1.5 million total amount that was in dispute. On the overdrawn bank accounts, we have instituted measures within the department. I believe there is a Finance circular that has just come out which is drawing agencies' attention to this, and I think that accords with the actions we have already taken within the department. The DSH Insurance matter has now been fully rectified and the department is very aware of the requirements for reporting.

CHAIR—ATSIS?

Mr Fileman—On the actions taken to rectify the situation, firstly ATSIS determined what were the correct indexation factors to have been used across the term of that nine years. We worked out what the correct indexation factors were and from that flows the amount of money which was then overcredited to the land fund and passed on to the Indigenous Land Corporation.

CHAIR—How much was that amount?

Mr Fileman—It varies but, in total, it is approximately $21 million in aggregate between the land fund itself, ATSIC and the Indigenous Land Corporation. Having determined what we believe was the correct indexation factor and therefore the correct amount of money, we then

agreed, with the Department of Finance and Administration, as to the amount, and that amount was repaid in full. That drew to an end the indexation factor error for the category A years. I will go forward to what is being done to ensure that a similar thing cannot occur—it cannot be the same, because category A years have now passed. Coincidentally, the land fund has moved from ATSIC, where it belonged. Now, with the abolition of ATSIC, it lives in the department of immigration.

Going from the old ATSIS CAC regime into the DIMIA FMA regime: DIMIA has commissioned an accounting firm to do a due diligence on the whole governance arrangements around the land fund to ensure that it complies with the FMA and so that any subsequent uses of indexation factors, albeit not for drawing down into the land fund but for on-paying to the Indigenous Land Corporation, are then done correctly.

Mr Hutson—The errors identified for the Department of Finance and Administration in the report were errors in reporting, and those errors have now been corrected.

Mrs Moody—A number of the errors in reporting by the ATO were fixed in the 2003-04 financial statements, because clearly we had information from the Audit Office about those issues before the report was published. The problem around one of the appropriations was related to our disclosure in the budget papers which we then used in our financial statements. That was fixed in the 2004-05 budget, and therefore the comparison of budget estimate and actual in the 2004-05 financial statements will now be appropriate. To the extent that we needed delegations and drawing right authority from the Department of Family and Community Services, that was received in 2004, and appropriate delegations issued in the tax office related to that authority from FaCS.

CHAIR—My question is to the Audit Office. You have conducted previous audits: *Special accounts No. 24, Special appropriations No. 15*. Can you outline to the committee what was in them? I know this committee investigated them but we have new members on the committee. What were the outcomes and recommendations of those reports?

Mr Cochrane—I think the main outcome from both the *Special accounts* and the *Special appropriations* reports was the fact that we found widespread noncompliance with legislative requirements. Interpreting what that meant for financial management in the Commonwealth, we were concerned that not enough attention was being paid to the management of legislative requirements. In a number of agencies there certainly was not enough attention being paid to making sure that there was knowledge of the legislative requirements, and what that meant for financial reporting and financial management was that they were not being kept in focus and up to date. So in going forward, the main concern from both reports, and I think from the committee's reports on special accounts, is that agencies have got to put into practice enough procedures to ensure that legislative requirements are being met—and met fairly consistently.

CHAIR—Since the *Special accounts No. 24 2003-04* report, have departments taken note of that and started to check themselves or is there a reliance on the Audit Office coming in and determining where errors in special appropriations have been made?

Mr Cochrane—We have not done a follow-up on special accounts but have focused our attention on the financial audit side—on special accounts in the current and previous rounds of

financial statement activity. We think that a number of the immediate issues in the special accounts area were corrected but I cannot say whether, on a widespread basis, agencies have put enough procedures in place to make sure these things do not reoccur in the future. I know that some are, for example, keeping, within their CFO area, an up-to-date register of their legislative requirements and they use it almost as a checklist as they go through every year to ensure that the requirements are being met. But we have not gone forward and done another in-depth audit in the special accounts area.

CHAIR—I have a question for the Department of Finance and Administration. What level is the chief financial officer in the SES ranking in the departments?

Mr Hutson—That would vary according to the agency concerned.

CHAIR—Perhaps you could give me some examples, for the various departments that are here. Attorney-General's Department, what level would your CFO be?

Mr Kennedy—SES band 2.

CHAIR—Department of Veterans' Affairs?

Mr Bayles—SES band 1.

CHAIR—ATSIS?

Mr Fileman—Executive level 2.

CHAIR—Department of Finance and Administration?

Mr Hutson—Ours is an SES band 2 officer.

CHAIR—And the ATO?

Mrs Moody—SES band 2.

CHAIR—Excuse my ignorance, because I do not know all of the bandings. What sort of income would band 2 and band 1 people be on? Surely you must know; some of you are those people and you are getting paid it. It is a matter of public record.

Mr Bayles—SES band 1 packages, I think, are about $140,000 per annum.

CHAIR—And a band 2 package?

Mr Hutson—A band 2 package would be moving up about another $30,000 or $40,000 beyond that, I would have thought.

CHAIR—So $150,000 or $160,000.

Mr Hutson—That is probably a bit high for salary. It depends on the agency concerned. Salaries actually vary across agencies.

CHAIR—I accept that. One of the questions that I have is: were any of these CFOs or their underlings paid performance bonuses in relation to the management of their departments in the last financial year or the financial year before that? Don't be silent; don't be shy.

Ms Blackburn—In the case of Veterans' Affairs, yes, quite a few SES officers received performance pay. The information is confidential in relation to individuals, but it could well be expected that the then CFO would be amongst that group.

Senator HOGG—Try the last five years.

CHAIR—Okay, we will be general. The last five years? I am not asking for individual names or the exact amounts. I am just asking whether performance bonuses were paid to CFOs and those involved in the audit process internally during the last five years. Attorney-General's?

Mr Kennedy—Yes.

CHAIR—Thank you. Veterans' Affairs have already said yes. ATSIS?

Mr Watson—We would not have specific information with us, but there is no doubt that performance bonuses have been paid to a range of SES officers within ATSIS. I have no doubt in assuming that over the five-year period the CFO would have been in receipt of one.

CHAIR—Finance and Administration?

Mr Hutson—I would reiterate the comments that Pat Watson made. Performance bonuses are paid. I imagine over a five-year period they would have been paid.

CHAIR—The ATO?

Mrs Moody—Yes.

CHAIR—So performance bonuses have been paid to very high-paid government employees who did not have the ability to pick up the fact that they were drawing down money from accounts that they should not have been drawing down from and that they did not have the ability, through internal audit processes, to pick that up. It was only picked up when the Audit Office came in. Some of you have questioned about legal argument et cetera. As a person who represents a community, the taxpayers that pay not only my wages but also the money that drives your departments, I would like to know why people are paid performance bonuses when they have not got under control one of the very essences of where their money for expenditure comes from. You might like to elaborate on that. Don't be shy.

Senator HOGG—Don't be shy; we're all friends.

Mr Kennedy—In the case of the Attorney-General's Department, some of these issues go back a number of years. I would just have to emphasise what I said in my opening statement: the

department had always believed that it had reported its special appropriations correctly. There were some issues with some of the appropriations that could perhaps be said to have been an administrative oversight. I would also like to emphasise the fact that all expenditures with regard to the three special appropriations in particular were reported in the department's financial statements. There was no understatement of expenditure or omission of expenditure. It was simply that we had not reported them against the correct special appropriation. The department also relies on—

Senator HOGG—Can I just stop you there. That is a major error. You just cannot come in here and say, as if it was an unfortunate accident, 'We're sorry it happened and we'll go out of here this afternoon and thanks very much.' That is a systemic problem that has been described to us.

Ms GRIERSON—And specifically with the Attorney General's Department you had used an appropriation under the Commonwealth Places (Application of Laws) Act, but you were unable to quantify that payment and you had not collected relevant data about that. That does not seem like an oversight to me—that seems unacceptable.

CHAIR—A belligerent attitude.

Mr Kennedy—We do not draw down money against that particular special appropriation. It is the case that the department administers that piece of legislation, but any moneys drawn down against that special appropriation would be made by other agencies. The department had not included that special appropriation in its financial statements but it is not in a position to actually know—or it had not been in a position to know—what had been drawn down by other agencies against that special appropriation.

Ms GRIERSON—Yet you are the parent body for that agency?

Mr Kennedy—For that legislation, yes. That would be one way of looking at that.

CHAIR—Perhaps we could hear from DVA.

Mr Bayles—The illegal drawing down of money that occurred in our instance related to the Compensation (Japanese Internment) Act 2001. The amount identified by the Audit Office was a figure of $1.5 million, which was an upper limit. That figure of $1.5 million was included in a significant figure covered in a section of that particular act. The issue was that the legislation was not explicit enough in its terms. It appropriated a set amount of money, which included the $1.5 million department funding that we have used. The problem was that the act did not split the administered money from the departmental funding—it just had one figure which included both. So the issue was that the legislation was not explicit enough and was not clear enough.

CHAIR—Who's fault was that?

Senator WATSON—Who drew the legislation up?

Mr Bayles—We did. At the time we felt that it was correct legislation and that it gave us the authority to do what we needed to do.

CHAIR—So, in essence, you were in breach of section 83?

Mr Bayles—The legislation was not explicit enough so, yes, that is correct. It was a section 83 breach because the legislation did not provide the authority to draw down the money. The money was not the full $1.5 million.

Senator WATSON—But you knew what was required; you knew what the money was for.

Mr Bayles—Yes.

Senator WATSON—Surely you could follow your own legislation, which you gave instructions for.

Mr Bayles—We gave instructions, obviously, for the drafting of the legislation. We felt that that was adequate. The amounts were reported in budget statements. We had the money—the draw down—approved by the department of finance. The intention of the government of the day was clear in terms of the amount of money that was to be used for departmental purposes. It was not until 2003-04, when the Audit Office came through, that it formed the view that the legislation was not correct or not explicit. It was not the full $1.5 million, because there were two pieces of legislation which provided for the payments to the POWs (J). One is the Veterans' Entitlements Act—and regulations that were made under that act—which provided the payments for the POWs (J) and their widows. The other piece of legislation was the Compensation (Japanese Internment) Act, which provided for payments to civilian internees and their dependants. The amount that was illegally drawn down was the portion of the $1.5 million that related to the administration of the payments for the civilians and the widows, so it was only a portion of that $1.5 million that was illegally drawn down. We estimated that amount to be $250,000, and it was paid back.

Senator WATSON—From what we have heard today there appears to be a lack of adequate documentation and record keeping in identifying amounts under specific pieces of legislation. I am surprised that a register is not kept which has, amongst other things, a check list with special requirements—for example, instructions from the Department of Finance and Administration identifying officials who are authorised for drawing down, what accounts and records need to be kept for appropriations and such matters. I find it very difficult to comprehend that you do not have this register, an authorisation under a certain act of parliament, the amount of money, and the processes and procedures that must be followed.

It also concerns me that we seem to be getting qualified accounts which the secretary of the department is not taking due responsibility for. It is all very well to say, 'It has been going on for years; it is the responsibility of the finance department.' At the end of the day, when you get a qualified financial account, it is the secretary of the department who I am concerned does not appear to be fulfilling their full responsibilities. I would like some comment from the witnesses. Do you keep these registers, do you keep these check lists that have to be ticked off, and do you have people who are authorised to do the draw downs?

Mr Hutson—Finance has produced quite a lot of guidance in the last few years to assist agencies in meeting their obligations under the compliance framework.

Ms GRIERSON—Does that mean circulars?

Mr Hutson—It means more than circulars. It includes a number of features. First of all we have a series of finance circulars, many of which are listed in our submission. More broadly than that, we have now produced 15 booklets in our financial management guidance series to advise agencies about how they should conduct themselves on various matters concerning the financial framework. We also have estimates memorandums and there are additional ones in preparation on a variety of issues that will come out in due course.

The point that I think Senator Watson was making is certainly the case as far as the legislation is concerned. The primary responsibility for the financial management of an agency rests with the chief executive. That is pretty clearly set out in the FMA Act, which provides that the chief executive is to provide for the proper control of Commonwealth resources.

CHAIR—I will go back now to the question I asked, because not every department had a chance to respond—and I would hate anyone to miss out. This was on the provision of advice to the chief executive on the action taken on matters of concern raised by either internal auditors or a report of the Auditor-General concerning the agency. The next in line, I think, was ATSIS.

Mr Watson—Chair, the question, I thought, related to performance bonuses paid to CFOs. We were going around on that particular question.

CHAIR—Yes.

Mr Watson—In the case of ATSIC, and we are answering questions on behalf of ATSIC, the situation had been going on for a period of 10 years. There was the application of an incorrect indexation rate that was only discovered when this particular audit was undertaken. Whether there may or may not have been performance bonuses paid to a CFO over a 10-year period is a bit difficult to fix once you have an audit report which identifies that a particular problem has been ongoing for some time.

CHAIR—I, along with the community—and I am sure my committee—would hate to think that performance bonuses are paid just as a matter of course; they want to believe that they actually mean something like performance and accuracy.

Mr Watson—I can only speak on behalf of ATSIS. Certainly, performance bonuses are not paid across the board to every SES officer. The CEO makes a decision as to whether a performance bonus should or should not be paid, and that goes to the performance of individual officers in undertaking their tasks.

CHAIR—Finance and Administration?

Mr Hutson—As I think I indicated, I am not directly familiar with performance bonuses, which are issued by our chief executive, but you would have to expect performance bonuses to be issued over a period of time in relation to people who have held those positions. I might put the issue in Finance's particular area into perspective in that what we had was an error in reporting rather than an error in drawing down an appropriation. I think there is a difference in

the heinousness of the crime, although obviously it is an important matter to get our reports accurate.

Ms GRIERSON—On that, if moneys are incorrectly drawn from the consolidated revenue fund, does that not mean loss of interest to the Commonwealth on that fund?

Mr Hutson—That depends. If money is incorrectly drawn from the consolidated revenue fund—that is, it is drawn without an appropriation—does that involve loss of interest? Potentially, yes, it does involve loss of interest. But frequently there are other valid appropriations which are available to meet the requirements of section 83.

Ms GRIERSON—No-one is going to go without, and we do not suggest that people are deliberately trying to defraud, mislead or misappropriate. But certainly inefficiencies breed more inefficiencies and therefore overall loss. It is not enough to say to us that these are reporting errors or that these are just inaccurate methods being applied. There is a cost down the line. We wonder, because we do not know if this goes on every year. The ANAO do not give us the whole picture and they did not do every agency and department. Somewhere along the line, those inefficiencies are eventually accruing some losses to the Commonwealth.

CHAIR—Do you wish to add any more to that?

Mr Hutson—No.

CHAIR—The tax office?

Senator WATSON—It is more than inefficiencies; it is lack of proper record keeping and documentation to make sure that the prescriptive requirements of the act are followed. That is what worries me.

CHAIR—We will come back to that in a second, Senator Watson; we will just let the ATO address the issue of performance bonuses.

Mrs Moody—In the tax office, the payments that were made should have been made. In some cases we did not report them against the right place but there was not actually any loss to the consolidated revenue fund because they represented valid payments to taxpayers that should have occurred. To that extent, probably the most significant issue was not having appropriate drawing rights from Family and Community Services concerning the family tax benefit. Again, the payments should have been made—the taxpayers were entitled to the money—but we clearly did not do well enough in getting the processes that sat behind that aligned.

It has shown us a couple of things that perhaps we were not as conscious of before. You could argue that we should have been—and we certainly are now—particularly around the interaction of the tax acts and the FMA Act. We are much more conscious and we explore that more actively now, whereas before we tended to think more in terms of what the powers under the tax act were. But there are interactions between those acts, and some of those issues where we did not do so well are actually about that interaction and understanding that.

The other thing that has caused us to think differently about some things is how the interaction of the general tax power under section 16 of the tax act and other payments that form part of the tax system—for instance, family tax benefit—interact. Therefore, because we are making a single payment to taxpayers, and that is the parliament's intention in putting those things together, we need to make sure that our reporting that sits behind that can say, 'Yes, we made a single payment but that is what it consisted of,' and to make sure we get that bit right. We were not conscious enough of some of those particular types of payment as they entered the tax system, to make sure our reporting was right.

On the specific issue of performance bonuses—trying not to be too defensive, personally, about it—the issue of performance bonuses for any executive relates to a range of activities that are undertaken in an agency. Particularly, for most of the CFOs, that also involves budget management and other administrative stuff. So this is one aspect. Certainly the executive take all those aspects, including audit reports, into account.

CHAIR—Members on this side have a performance bonus. It is called getting re-elected if we do everything right.

Ms GRIERSON—Does it always apply?

CHAIR—It might be an interesting topic for the Audit Office to audit performance bonuses paid through the SES. But that is a discussion for another day.

Senator HOGG—This performance bonus issue should not be viewed too lightly. Whilst, as Ms Grierson said, we are not accusing anyone of fraud, we are accusing people of general clumsiness at best. But, if this happened in the real world, in the commercial world, we understand that there would be a very dim view of it. In that sense, whilst you might put forward a range of other matters to be considered in deciding whether or not someone gets a performance bonus, this of itself would be sufficient, from what I understand, to be a severe black mark against their performance. I hear what you say, but I do not necessarily agree with it in that context.

CHAIR—I suppose the parallel would be, if it was a publicly listed company, ASIC would be taking appropriate action against that company.

Senator HOGG—You could say that.

Ms GRIERSON—Mr Bayles, you used the word illegal and that is exactly the other point—some of the actions taken were illegal under the legislation that we have, and that is a serious matter for us all to contemplate. There are penalties, and obviously none of us would want to see those apply. However, that is the way the legislation is framed, for a very good reason—if you deviate from our legislation, parliament's decisions, it is considered serious enough that you will incur consequences. With DVA and Finance, has everything being regularised again? Has the money been correctly appropriated now and paid back to the correct funds?

Mr Culhane—The short answer is yes. The amount that both DVA and Finance believe was incorrectly drawn from the consolidated revenue fund has been returned.

Ms GRIERSON—Can you explain to us why you anticipated an amount that was 90 per cent in excess of what you actually needed for the payments to prisoners of war of the Japanese?

Mr Bayles—Yes. An appropriation was made for payments to civilian internees and their widows. That amount has not been fully used and it remains in the consolidated revenue fund. The reason for the underestimate is that we thought at the time that there would be a large number of prisoner of war widows who would have to be paid under that act because they were not widows of veterans covered under the Veterans' Entitlements Act—in other words, they may have been widows, but they were not war widows.

As it turned out, we were wrong in our estimate and many of the widows who came forward to claim the benefit were in fact eligible for war widows pension. They were war widows and could therefore be paid under the authority of the Veterans' Entitlements Act regulations. We did not use the full amount of that money but we used more under the Veterans' Entitlements Act than had been originally estimated. There was a balancing between the two.

Senator WATSON—I do not accept the proposition offered by several agencies that there was no overall loss to or by the agency. The issue that we are confronting today is of allocating and drawing down under the correct appropriations authorised by the parliament. If this has not been followed, there is a serious breach.

CHAIR—Would any of the departments wish to answer that—how they treat the seriousness of these breaches and what action has been taken? Has any disciplinary action been taken against any members of the executive for these breaches?

Mr Hutson—I am not aware of any disciplinary action which has been taken as a result of these breaches. The point that Senator Watson makes about these breaches being considered seriously is absolutely right. I understand that breaches of section 83 of the Constitution result in an audit qualification almost automatically. Is that correct?

Mr Cochrane—Yes.

CHAIR—I suppose I will liken it to this—if I was a taxpayer and I claimed wrongful deductions or put it into the wrong box or area, very serious actions would be taken. Is that correct, Mrs Moody?

Mrs Moody—That would depend. We would take into account the intent of the taxpayer in determining the appropriate penalties. We would determine whether there was actually a shortfall in tax and also whether it was a genuine misunderstanding on the part of the taxpayer or whether, in fact, it was more than a misunderstanding.

CHAIR—But I could be assured that the taxpayer would not get a performance bonus for misreporting?

Mrs Moody—We do not pay performance bonuses to taxpayers.

CHAIR—I have a question for the Department of Veterans' Affairs. Could you please explain to the committee why you did not disclose the payments totalling $31.321 million under section

39 of the financial management authority act special appropriations between the financial years 1998-99 and 2002-03. What procedures have you implemented to ensure that this does not occur in the future?

Mr Walsh—The moneys relate to the drawing down from the Commonwealth revenue fund for investment of reserves for the Defence Service Homes Insurance Scheme, which is basically money set aside for any large claims from our veterans and clients. The money that was not disclosed was disclosed in the Defence Service Homes Insurance Scheme's financial statements and also in the Department of Veterans' Affairs financial statements. However, it was not disclosed as a section 39 appropriation. There was a valid appropriation. The secretary had the delegation to use that appropriation and had delegated that to the general manager of the Defence Service Homes Insurance Scheme. In terms of moving forward, we corrected the disclosure in the 2003-04 financial statements and will continue to make that disclosure in future years.

CHAIR—I fire a question now to the department of finance in relation to inconsistency in appropriation management. Have you clarified your advice to departments on whether special appropriations expire at the end of each financial year? In particular, have you advised all agencies of your revised position to ensure conflicting advice is not given in the future?

Mr Hutson—Special appropriations do not always expire at the end of any financial year in the way that annual appropriations sometimes do. If you think of the special appropriation for the payment of pensions, for example, that is a special appropriation which continues year on year and never formally expires. If there is an entitlement to receive a pension, then the money is available to pay that pension.

Ms GRIERSON—I think there has been conflicting advice on that. Would ANAO like to comment?

Mr Boyd—I think the particular special appropriation in question relates to those called the supplementary measures, which relate to part of the agreement with the Democrats to introduce the GST. That is looked at on pages 72 and 73 of the audit report, examining, in a sense, the different approach taken by the five agencies administering the various special appropriations as to whether these particular special appropriations lapse or do not lapse. Conflicting advice was provided over time, leading to different approaches being taken by the individual agencies to administering those special appropriations.

Ms GRIERSON—Why is it significant whether they do or do not lapse?

Mr Boyd—It is significant if you take the example of the Australian Greenhouse Office, which was told that its share of the special appropriations does lapse, in the sense that if it is not used in this financial year it is not available next year. The Australian Greenhouse Office then went and obtained additional annual appropriations so that it could continue to pay the programs. As it now transpires, the most recent advice is that the special appropriations do not lapse. Effectively, what has happened is that the parliament has, through no fault of its own, appropriated the same money for the same programs on two different occasions.

CHAIR—That is on page 72 if you are looking it up.

Ms GRIERSON—I think that has to be clarified. What is going to happen in future? Are they all going to expire at the end of the year? There needs to be clear guidance to every agency and department so that they do not double dip, basically.

Mr Culhane—The terms and conditions of each appropriation vary broadly and are set out in the act. If you take at one extreme an act for social welfare payments, they are typically open-ended in duration. This specific example that is dealt with in the audit report is, if I recall correctly, a single appropriation or perhaps three different appropriations in one act. Based on the ANAO's analysis, or at least the agency's analysis at the time, it seems there was a lack of clarity as to whether these appropriations went on for a lengthy duration or whether they were finite. The problem that has been identified by the Audit Office here is not a problem that is typical of all special appropriations. I would suggest that it is isolated to this particular appropriation act.

Ms GRIERSON—But you would need to know, wouldn't you, if you were administering those moneys, if it must be spent by the end of that period or whether it is an ongoing allocation or appropriation.

Mr Culhane—That is correct.

CHAIR—Whilst we have Finance here, going back to nondisclosure and investments under section 39 of the FMA Act, can you explain to the committee why you did not disclose the payments totalling $95.098 million under section 39 of the FMA Act, special appropriations, between financial years 2001-02 and 2002-03, and what procedures you have implemented to make sure this does not happen again.

Mr Culhane—Regarding those special appropriations that were drawn on which were not reported in the financial statements at the time, the department no longer draws on section 39 of the FMA Act. If you like, it is analogous in one sense to ATSIS's experience where the practice of drawing on that special appropriation to make investments is no longer undertaken by the department. So, going forward, there is nothing to report against the appropriations. The issue has been drawn.

CHAIR—Why wasn't it disclosed at the time?

Mr Hutson—I think it was an error at the time.

Ms GRIERSON—I would like to clarify the ATSIS overpayment. What is the current status in terms of repaying that?

Mr Fileman—The amounts have been determined as to how much was overdrawn. Those have been repaid. In addition, a calculation was made as to how much interest was earned on those overcreditings and that has also been repaid.

Ms GRIERSON—Finance, did you negotiate that amount and confirm that it is the correct amount?

Mr O'Neill—Yes, we did.

Ms GRIERSON—And you are satisfied that that has all been addressed properly?

Mr O'Neill—Yes, we are.

CHAIR—Here is a question for each of the departments. Can you explain to the committee the processes you have now implemented which give you a clear understanding of the full amount drawn under each special appropriation? We will start with Attorney-General's.

Mr Kennedy—We currently draw down against three special appropriations. We have separate ledger codes for those appropriations. We have a procedure with our HR area, which makes some of those payments, to advise us if there are any new payees or any changes to the current payment arrangements. The hand gun buyback program is administered by a separate area in the department. Again, there is a full set of separate ledger codes set up for that area to use. Those expenditures are reviewed both by the area itself against the requirements of the legislation and by people in my branch. The ongoing payments for the two former solicitors-general, as I mentioned earlier, will continue. There will be no additional payments to those. We simply monitor that ledger code to ensure that only those payments to those solicitors-general have been made.

CHAIR—And for the DVA?

Mr Bayles—We have a number of special appropriations to pay pensions and provide health care and other benefits to eligible veterans and their dependants. We have separate ledger codes for these appropriations. Expenditure against those appropriations is reported on a monthly basis to the executive of the department. We have full reporting of expenditure against those special appropriations in all of our financial statements. We have a drawing rights register which records the officers who have the authority to draw down money. Our expenditure against special appropriations is very closely monitored by the Department of Finance and Administration.

CHAIR—And for all of these draw-downs within each of the special appropriations it has been clarified by DOFA or the Audit Office that you are drawing them out of the correct areas?

Mr Bayles—Yes. We have constant scrutiny by the Audit Office and Finance over the correct draw-down of money from the special appropriations.

CHAIR—Audit Office, do you have any comment on that?

Mr Boyd—I imagine the chief finance officer is referring to the annual financial statement audit process. In terms of what we examined with the Department of Veterans' Affairs, at the time we examined it for the Compensation Act there were essentially two errors. The first error was that the full $1.5 million was reported against the Compensation Act. As they have reported, $250,000 has now been returned as it cannot be repaid out of either act. On top of that, that would therefore mean the remainder of the $1.5 million—$1.25 million—was recorded against the incorrect special appropriations when it should have gone against the Veterans' Entitlements Act. As to what is currently happening, as our audit is finished, we could not opine on what the current procedures may be.

CHAIR—Do you report to the Audit Office through your chief officer as to appropriate measures you are now taking?

Mr Bayles—We advised the Audit Office of our intention to repay an amount of money to the consolidated revenue fund—the $250,000. We advised them that that was our intention before it did it and we had consultations with the Department of Finance and Administration in agreeing on that figure. So we informed them that that was the corrective action we had taken.

CHAIR—So the next time an audit is done on special appropriations you are sure there will be no 'wrong side of the ledger' for any payments—are you guaranteeing us that?

Mr Bayles—You are asking me to make a promise about something I really cannot give an undertaking on. But we will endeavour to do our very best to make sure that what we are doing is right, correct and legal.

CHAIR—Surely after this audit report each department has a better understanding of what the special appropriations apply to, so therefore it would be safe to assume that there will be no inadvertent wandering off and drawing down on the wrong fund?

Mr Bayles—I can assure the chairman that we have learnt some lessons from this particular audit report.

Ms GRIERSON—I will explore that point a bit further with Finance. If you do not draw down under the correct legislative authority then the problem continues. So we have seen poor drawing controls and then we have seen poor recording of it and poor reporting of it. But if you do not get it right in the first place and you are not using the right legislative authority for appropriating or drawing on funds, that is the starting point. If we could fix that starting point, it might really be something to celebrate, almost.

CHAIR—Have a performance on it!

Ms GRIERSON—Have you done enough and are you doing enough to make sure in the future that everyone is identifying correctly the authority they have by the legislation to draw on moneys?

Mr Hutson—Thank you for the question. I might pass across to my colleague Ms Hazell in a minute. Finance has a thing we call the CAMM system, which is basically our cash management system for handing out cash to agencies. Under that system there are estimates provided against each of the authorities. But when it comes down to the question of drawing against those authorities, whether or not that is the correct drawing against the authority is really a matter for the department concerned.

Ms GRIERSON—I know that is a good point, but let me interrupt. So your check is more or less to see whether it is within the estimate: you are looking all the time to make sure that no-one is moving too far from that estimated amount—that is your check and balance that is constant—but you are making an assumption that it is coming from the right place.

Ms Hazell—When agencies draw down funds through system finance, if it is an annual appropriation, we check to make sure there is still appropriation available. Where it is a special appropriation, if the agency has made an estimate and the draw down would exceed that estimate, we then refer it back to them to talk to the relevant area in Finance to agree a new estimate, and we are notified of that before we proceed with the draw-down. However, it is the agency's responsibility to choose the right special appropriation for the payment they are about to make.

Ms GRIERSON—Would the Audit Office agree with that—the agency or their parent portfolio?

Mr Boyd—Yes. That is given force under the Financial Management and Accountability Act, through the delegations. Individual chief executives are delegated the power to issue drawing rights. You need a valid drawing right before you make a payment, a public money request or debit an appropriation. That has been delegated to chief executives who generally on-delegate that power. It is up to the individual agency concerned to make sure that their controls and procedures meet those requirements.

Ms GRIERSON—So it would help you a lot if they did that, wouldn't it?

Ms Hazell—It would help the accuracy of the records at the end.

CHAIR—Going back to the original question that I asked of Finance: could you please explain to the committee the processes you have now implemented that give you a clear understanding of the full amount drawn under each special appropriation.

Mr Fileman—For Immigration it is somewhat academic now. The special appropriations occurred between 1995 and 2004—30 June 2004 was the last of the category A years where the appropriation was able to be drawn. There is no special appropriation going forward.

Mr Hutson—Our areas for the department were primarily reporting, and those areas have now been corrected—which was the story that you heard before. More generally, now we have a complete list of the special appropriations, we have got to the point where we have been able to allocate almost all of them to a particular department. We expect to complete that work of allocating the special appropriations by the end of this year, so that agencies are able to accurately report on their special appropriation.

CHAIR—Can you take on notice to report back to this committee on the actions that have been taken, and the outcomes?

Mr Hutson—Sure.

CHAIR—I will move now to the ATO.

Mrs Moody—As I mentioned previously, we sorted out most of our reporting issues in the 2003-04 financial statements, with a flow-on into how we disclosed some estimates in the 2004-05 budget. We are also putting in place special appropriation ledgers, which will be in place by the end of April, but we already have processes in place that allow us to report against those

different special appropriations. As part of that, we have developed allocation rules so that, when we make a single cash payment and we then need to split that in cash terms back to the different appropriations, we have agreement with the ANAO about how we will go about that.

We are also putting in place processes around new policies so that, as new policy comes up, we are actively exploring both the appropriation and the drawing rights issues at the time that the new policy is being developed, to ensure that we understand both the accounting reporting and payment responsibilities that occur as that is being developed rather than when payments are suddenly being made at the end of the process.

Senator WATSON—I have a question for the Australian National Audit Office. In your brochure you state:

In some instances, entities have obtained more than one appropriation for the same purposes.

I can understand the department coming back to parliament for an additional appropriation where the original estimate was less than what was required in terms of their forecasting—for example, for a gun buyback or a whole list of situations where it would be very difficult because of the lack of raw data on which the client base is to be determined. Apart from that circumstance, where there has been an estimate in the initial requirement, who of the responsible entities have obtained more than one appropriation for the same purpose?

Mr Bond—The example we drew in the report was in respect of the Appropriation (Supplementary Measures) Act, which my colleague Brian Boyd referred to earlier. The first example he referred to was the Australian Greenhouse Office. I am being advised that its appropriations lapsed for the program funded under the Appropriation (Supplementary Measures) Act and it obtained additional funding through the annual appropriations. In the companion act, the Department of Family and Community Services overlooked the fact that it had a $15 million per annum appropriation in respect of the Supported Accommodation Assistance Program, and it returned to the budget and obtained that money under Appropriation Bill No. 2 in the appropriation years. That is on page 49 of the report.

So for those two acts in particular we came across current examples of additional appropriations being obtained when there was an existing special appropriation in place. If I might comment more broadly, there are some 414 special appropriations in existence that we found at the time of the audit. Many of them have overlapping purposes or indeed one may substitute for another. We discovered that many appropriations, even though they were not used, were not reported on. That is, you may have an alternative valid appropriation, you may use appropriation (a) and you may report that in your financial statements. You may also be responsible for another appropriation which could equally effectively be used to draw money and pay for the same purpose. It is a tenet of reasonable management to disclose all possible sources of funding, including the exact cheque book you did use as well as the other cheque books you have in your drawer which may be used for the same purpose.

Senator WATSON—Has remedial action been taken for all of those circumstances you outlined?

Mr Boyd—I guess in terms of remedial action, if the concern was that it is a poor control to have more than one appropriation for the same purpose, the challenge with special appropriations is that, as they are in a law passed by the parliament, which is a requirement of the Constitution, you would actually need to either amend or appeal certain pieces of legislation to remove the duplicate special appropriations. Obviously, going forward, the other control we would encourage is that agencies be aware of what appropriations already exist before requesting further appropriations.

Mr Bond—And, I might add, to report on appropriations that are not used as well as those appropriations which are used in a period.

Senator HOGG—It has been a very good roundtable today, but I have a question that goes to the overall conclusion, and Finance are probably the best to address it. The ANAO said that there have been significant shortcomings in the financial management of special appropriations. ANAO were surprised with the findings which resulted in only one agency out of the 43 able to satisfy all the ANAO audit objectives for the financial management of special appropriations. The audit findings indicated that sound levels of governance, management and reporting of appropriations across a majority of agencies did not exist. That also goes very much to the issue of the professional standards that exist across the board in the various agencies and departments. What action has been taken through Finance to address the issues of the adequacy of the professional qualifications of the people responsible? What remedial action has been taken to ensure that those people who are responsible are able to address the issues that have been raised?

Mr Hutson—In short, the way the legislation operates is perhaps—to tell a story which has already been told—to put all the responsibilities in this area firmly in the hands of the chief executive. That is not to say that Finance and indeed the Audit Office have not contributed to assisting chief executives in this area. We have a publication entitled 'The role of the chief finance officer' for departments, which indicates the sorts of things that agencies might take into account.

Senator HOGG—But unfortunately those things tend to get filed on a shelf somewhere or in a bookcase or whatever. What proactive steps do you take?

Ms Hazell—In regard to raising the profile of the chief financial officer in departments and raising, if you like, the professional qualifications of those people, there is not only the best practice guidance issued by the department of finance but also for a number of years we have every so often issued a survey of the departments to see whether the general standard has been improving. We are currently as a department collating the results of the most recent survey. It is unfortunately not in my area of responsibility, so I cannot really give you a heads up on what it is finding. But I know that from the previous survey there had been a general improvement in the level of qualifications and, if you like, the place that chief financial officers occupied within the organisation and their access to the senior executive of that organisation.

Senator HOGG—But does that survey look at their capacity and ability to perform in the role they have undertaken?

Ms Hazell—It goes to professional qualifications.

Senator HOGG—I concede that professional qualifications are one thing, but you can have the brightest person in the world and if they do not have the capacity to do the job then you have another problem—a real problem, indeed. So I am trying to see if you test that as well.

Ms Hazell—It is a very difficult area to test, and I suggest that it is the role of the chief executive of each agency to make an assessment as to whether their chief financial officer has the capacity to do the job expected of them. We were referring to this survey as a way of trying to raise the profile and have agencies focus on the need for these people to have the sorts of capacities we have been talking about.

Senator HOGG—I reckon most of them would be ducking for cover at this time, given the evidence before this committee today. If I were them, I would be ducking for cover as well, because this report of the ANAO has reflected badly on every agency.

CHAIR—Bar one!

Senator HOGG—Sorry, bar one.

CHAIR—Which agency is that, by the way?

Mr Boyd—The Australian Industrial Registry.

CHAIR—What is their budget?

Mr Boyd—I think they have one special appropriation of approximately $1.2 million per annum for the pensions of retired justices of the Industrial Relations Commission.

Senator HOGG—Thank you for that help, Chair. I appreciated that assistance. It concerns me greatly that this has come before the JCPAA and that the ANAO has had to go to the extent that they have gone to—and I congratulate them once again—to pick it up through a performance audit. I also put it on the public record that I cannot understand why this was not picked up in financial audits in the years prior to 2003-04, seeing that the act has been operating for at least five years. Was the better practice guide that Finance put out developed purely within Finance or was it developed in conjunction with the ANAO and other agencies?

Mr Hutson—I must admit that I am not familiar with the development process of that, but the publication was certainly put out by Finance.

Senator HOGG—Can you take that on notice and let us know when the better practice guide was developed, who developed it and whether there was any consultation with ANAO. I ask the ANAO: are you aware of the better practice guide and were you consulted in its development?

Mr Cochrane—As far as I can recollect, I do not think we have been involved in the preparation of the guide.

Mr Boyd—We are certainly well aware of it.

Senator HOGG—From what you have said, you are obviously well aware of it. Given your interest in this area, would you have expected to have been involved in the development of the better practice guide?

Mr Cochrane—I think it would have been nice, but certainly Finance—

Senator HOGG—I am not interested in niceties; I am interested in practicalities.

Mr Cochrane—We have some hard experience to feed into a better practice guide. I am not saying we were not consulted. I certainly do not think we have been consulted formally, but I cannot say at the moment whether any of our research and development areas have been spoken to.

Senator MOORE—Following on from Senator Hogg's question, the Finance submission indicates that there are a range of circulars and best practice guidelines out there, and I know that is the way the process is operating in our public sector with its current devolved nature. My understanding is that, with the skills and professionalism of all the people who work in finance areas, there is a certain collegiate responsibility. Most of those agencies are in Canberra, and I think most agencies have their centralised finance areas in Canberra. I am interested in what opportunities there are for people in those areas to get together as a group and develop their own training and professionalism. This seems to me to be the kind of initiative that should stimulate something of that nature. I know there are ongoing responsibilities and so on, but it seems to me that such an audit report, which highlights such an issue, should stimulate some kind of special seminar, special training proposal or special meeting involving people in each of the agencies. I know that you cannot dictate that, and that it is only recommendatory, but it seems to me that this would be an opportunity for people to learn and to develop communal better practice. Is there any opportunity for that kind of activity amongst finance people in our national capital anymore? My understanding is that this kind of thing happened in the past.

Mr Hutson—Certainly Finance is stepping back very much into the training game. We have an agreement with the University of Canberra to develop training programs internally for the department of finance, to upgrade our own internal training, and to make that available to the broader public service. You also raised the question of what opportunities there are for chief finance officers to get together. We do have a CFO forum which meets once a month and addresses issues of current interest in the financial management of the Commonwealth, which goes beyond special appropriations to budget issues and various other matters that emerge.

Senator MOORE—Has this issue made it onto the agenda at any of those meetings?

Ms Hazell—Yes. In one of my former lives as an attendee of that forum, I can assure you that it did make it onto the agenda.

Senator MOORE—It is a really important point in terms of information from all of you to us as a result of this process. I know there were difficulties in it and with people having different interpretations, but if the people involved at least discuss it amongst themselves then that gives us some confidence and a way forward. To the best of my knowledge that had not come out before.

Ms GRIERSON—And it does seem an excellent suggestion because we have done the special accounts audit, which was appalling, and the special appropriations is no better. We still have the investment of public funds and the net appropriation agreements audits to come, so we are very much looking for improvement; we are hoping that those two will be outstanding. We do not know, though; they are just concluding or in progress. I just want to clarify one thing about mirror taxes. Has there been a decision on who is going to report on that or who is going to disclose that? Has that been clarified, because the audit did point to some difficulties in that area?

CHAIR—We will start with the Attorney-General's Department, which it was put to. Perhaps they should be reporting on it, but I understand they have concerns about reporting on something that they have no expenditure control over.

Mr Kennedy—I wonder if you could repeat the question.

Ms GRIERSON—What was actually found was that the Attorney-General's Department suggested it would be more appropriate for the act to be made the responsibility of a central agency, such as Finance. The Attorney-General's Department commented that when the mirror taxes from the states and territories are collected incorrectly, but you do not want to deny them that revenue so you put it under a different appropriation, then it might be best if there was a central disclosure of the reporting of that. I would imagine it is a bit of a nuisance. It is an accounting system that has to be done. There are no actual flows of moneys particularly, but it seems that central reporting was suggested by your department. I do not know if Finance is aware of that or whether that has been followed up.

CHAIR—It is on page 39.

Mr Kennedy—That particular piece of legislation, the Commonwealth places act, is one, as I mentioned previously, the department does not draw down on itself. We really are not in any position at all to know how widely spread that particular special appropriation is. It was a suggestion I had made at the time that it could be better managed perhaps on a centralised basis where agencies might feed into a central point and where there may be more capacity than there is in the Attorney-General's Department to actually administer that across what could be a wide number of agencies. It was both an oversight role and an administration role that I had suggested at that particular time.

Mr Hutson—This is one where we might need to enter into some further discussions with our colleagues in the Attorney-General's Department. The bottom line is that the administrative arrangements orders allocate responsibility for legislation to portfolios. That is where the responsibility lies and that is the way the system runs. This particular piece of legislation is with the Attorney-General's portfolio. I am not sure that Finance would have any particular advantage in terms of capturing and adding up the numbers. It is an administrative task, as I think you acknowledge, which has to be done by somebody.

Ms GRIERSON—But someone has to know the final outcome of all that.

Mr Hutson—That is right, and there is no particular advantage in Finance knowing the final outcome because, as Attorney-General's point out, there is no direct flow of cash through the Commonwealth system.

Ms GRIERSON—Audit Office, would you have a view on that?

Mr Cochrane—I think we are very much in Finance's camp at the moment. It is clear through the AAOs that the departments and agencies have responsibility. I will say that mirror taxes legislation is hard to administer unless you are actually thinking about it and planning it. It is not an easy piece of legislation. But we have to recognise that underlying it is that the CRF is actually self-executing—we are using a Commonwealth power in place of a state power to raise money and, in effect, it is an automatic in and out of CRF. So it should be recorded, in other words.

Senator WATSON—Could each of the agencies at the table state whether you have an audit committee, how often those audit committees operate, and whether you have a comprehensive internal audits function.

Mr Kennedy—We have an audit committee which is chaired by an independent person of suitable experience. There is another external member on that committee as well as two departmental representatives. The Australian National Audit Office attends those meetings, which are held every three months. We have outsourced internal audit arrangements, and the audit committee agrees on a program of reviews. It is a very active program, and we have a fairly extensive process of managing the recommendations and ensuring that they are implemented by the correct area within the department. Follow-up reviews are also conducted.

Senator WATSON—Have any of these issues been brought to light by either the audit committee or the internal audit?

Mr Kennedy—These issues have not been subject to an internal audit review.

Senator WATSON—Or discussed by the audit committee?

Mr Kennedy—They were certainly raised by me at the audit committee following the ANAO review. The department has a range of issues and limited resources within which to conduct audits, so there is a priority setting arrangement which occurs and which seeks to manage the major risk areas within the department. I am not saying that special appropriations is not a major risk area by any means, but there is a process that is—

Senator WATSON—Compliance is a major issue.

Ms Blackburn—In the Department of Veterans' Affairs we have a national audit and fraud control committee chaired by the deputy president of the Repatriation Commission who reports directly through to the secretary. That committee meets quarterly. We have a highly qualified, independent representative on that. ANAO attends all of our audit committee meetings. NAFCOM is supplemented by state audit and fraud committees. We also have an outsourced internal audit arrangement and we have recently appointed a new audit partner, KPMG, so that

there is considerable focus within the department on audit reports, audit planning, risk planning and fraud control.

Senator WATSON—Are these sorts of matters raised by internal audit or by the audit committees?

Ms Blackburn—Yes. We have very comprehensive reporting on what audits have been conducted in the department by ANAO and on which other audits conducted elsewhere have some bearing on our departmental operations. There is also extensive reporting on the internal audit program, including follow-up action which arises as a result of those recommendations.

Senator WATSON—What came out of these committees and internal audit functions as a result of the matters that we are discussing today?

Ms Blackburn—The assurances that the department follows appropriate procedures so that these matters are discussed at the audit committee—

Senator WATSON—And they were raised at the audit committee?

Ms Blackburn—Yes—and action taken to ensure that we have appropriate procedures in place.

Senator HOGG—That was post the event, though; that was not prior to.

Ms Blackburn—In this particular case, post the event. In other cases we are looking at internal audit reports and what action needs to be taken.

Senator HOGG—Senator Watson and I have had a little discussion, as you might have worked out. We are interested in why no internal audit committee flushed this out in the first instance. What are their functions? What are their roles? It is not much use acting post the fact. They are there to pick up the extraordinary rather than the ordinary, in my view. Any dope can pick up the ordinary, surely. They are there to pick up the extraordinary. We are not blaming people there. This was systemic across all of the agencies, almost. It surprised us—and I am reflecting on the discussion that Senator Watson and I had—that not one internal audit committee picked it up. For that matter, it took a rigorous performance audit by the ANAO to pick it up, so one can say there is a mitigating factor there. Nonetheless, that is why we are interested in what your internal audit committees do.

ACTING CHAIR (Ms Grierson)—Would ATSIS like to go on?

Mr Fileman—The organisation that these breaches occurred within was, of course, ATSIC. ATSIC is now abolished, so going forward there is no audit committee. Did it have an audit committee prior to its demise? Yes, I believe it did. It had a regular and normal operating audit committee.

ACTING CHAIR—Finance?

Mr Hutson—Finance actually has two audit committees. One is the one which almost every department has. It was chaired by the former general manager of my group who has now left the department. That committee has an independent member on it. Members of the Audit Office attend the committee meetings. It meets bimonthly. It is certainly relied upon by the chief executive in terms of signing off on accounts and various other matters. In addition—and I am supporting the committee—we have a very strong internal audit function. We have chosen to contract out our internal audit function to PricewaterhouseCoopers. They are currently expanding the amount of space they have, so they are obviously obtaining more resources to undertake a greater scope of work than they have done in the past. The other audit committee we have provides advice concerning the consolidated financial statements of the Commonwealth. So it is separate from the department's accounts; it looks specifically at the consolidated financial statements of the Commonwealth.

Senator HOGG—Why do you think your internal audit committee did not pick up the difficulties that you were having?

Mr Hutson—You mentioned that it is not the ordinary, it is the extraordinary. The issues which were identified with respect to Finance—as indeed in respect of most of the agencies that are represented at the table—are actually quite technical matters. In some cases agencies have acted on advice which they had which has subsequently been proven to be erroneous. To the extent that an audit committee will probe the issue of whether you had obtained proper advice, the answer was that proper advice was obtained—it is just that there was a difference of opinion later down the track.

ACTING CHAIR—ATO?

Mrs Moody—The ATO has an audit committee. It meets approximately every two months, and perhaps slightly more frequently during financial statement periods. It also has an internal audit function which is in house. The ANAO performance and financial statement audit people normally attend the audit committee meetings. There was no internal audit of related issues prior to this. Certainly once the Audit Office findings were known—and this was even before the report was published—and we became aware that we had issues, the audit committee discussed those and the chair of the audit committee met specifically with Mr Boyd and Mr Bond to discuss those issues and how they related to the ATO to ensure that we both understood what those issues were and were also taking immediate action to fix any of those issues.

CHAIR—Recommendation No. 2 of the audit report reads:

ANAO recommends that Portfolio Departments review their processes for providing information to the Department of the Prime Minister and Cabinet for the purpose of updating, consolidating or amending the Administrative Arrangements Order, in order to confirm that the information provided is accurate and includes all relevant legislation administered by their Ministers.

Have each of you provided PM&C with accurate and up-to-date advice in relation to your administrative arrangement orders to ensure that you report on all special appropriations for acts that you administer? The Attorney-General's Department does not have special appropriations, does it?

Mr Kennedy—We do.

CHAIR—Okay.

Mr Kennedy—I do not believe that we have reported or liaised with PM&C. There is always that issue post election, but the issue is perhaps more the other way around: it is the department being fully aware of all of the special appropriations in legislation that is actually administered by the Attorney-General.

CHAIR—What is the Department of Veterans' Affairs response?

Mr Bayles—We have taken action to implement that recommendation.

CHAIR—Okay. What is ATSIS's response?

Mr Fileman—The special appropriation ceased on 30 June 2004.

CHAIR—What about Finance?

Mr Hutson—I have the same answer as the other ones: yes, we have taken appropriate action, I am sure.

CHAIR—You have conferred with PM&C?

Mr Hutson—No, I do not think we have necessarily conferred with Prime Minister and Cabinet. One of the things which Mr Culhane mentioned earlier was that we are going through a process of ensuring that all of the 414 special appropriations are appropriately allocated. That is a task which is ongoing. We have also agreed to take the outcome of that on notice and to provide an answer to the committee.

CHAIR—It is just that recommendation No. 2 was specific about providing information to PM&C.

Mr Hutson—Yes, it was. The recommendation was to review our processes for providing information to PM&C, not to actually provide information to PM&C at this point. This is perhaps a moot point but the point I am trying to make is that we have been going through a review of all 414 special appropriations and we have agreed to take the outcome of that review, which is not yet completed, on notice and advise the committee.

CHAIR—What about the ATO?

Mrs Moody—We are not actually a portfolio department, so that would be through the Department of the Treasury.

Senator MOORE—I have a question to ATSIS. In terms of the process, this occurred with an appropriation code that used to be handled by ATSIC/ATSIS and now has gone to whichever of the new departments it has gone to—I should know but I cannot remember.

Mr Fileman—Immigration.

Senator MOORE—Has the receiving department had a full briefing on this issue?

Mr Fileman—Yes, they have.

Senator MOORE—So they have taken all the corporate knowledge that went with this process and taken it into the new place?

Mr Fileman—That is correct.

Senator MOORE—There were a number of other special appropriations that ATSIC/ATSIS used to handle as well. That was not the only one that ATSIC handled.

Mr Fileman—I know what you are saying—there were other special accounts; that is certainly true.

Senator MOORE—So the knowledge went through?

Mr Fileman—The knowledge has gone over. There was only the one special appropriation but there were two special accounts and they have gone to Immigration.

Senator MOORE—That is good. Thank you.

Senator WATSON—I have a question for the Australian National Audit Office. Recommendation No. 2, which has just been referred to, refers to PM&C. This concerns me. I would have thought that in relation to matters of procedure and control and finance the premier department would really be the Department of Finance and Administration. Do we have a split responsibility nowadays?

Mr Cochrane—No. It is simply that PM&C are responsible for the administrative arrangements order. The recommendation is directing agencies to liaise with PM&C so that we have got that order totally correct. Finance still have responsibility for oversighting the financial management framework.

Mr Boyd—PM&C actually draft the AAO for the Prime Minister's consideration. It is done in the Department of the Prime Minister and Cabinet. It allocates legislation, portfolio responsibilities, what ministers are supposed to be handling what, and so forth. The background to this is the findings of the audit in terms of some legislation not being allocated to anyone and some being confused as to who holds it and so forth. When we worked with PM&C, what they told us they were going to do as a result of this was that they would have their secretary write to each of the portfolio secretaries to remind them of or reiterate to them the importance of making sure that the input provided to PM&C in drafting the AAOs is both complete and accurate.

Senator WATSON—Has that caused any uncertainty in the minds of those administering Finance, because they really do not have the ultimate authority in issuing instructions to departments? Where does their authority finish and where does PM&C's start?

Mr Hutson—Special appropriations are contained in legislation which is allocated to portfolios. The role of the allocation is very much with the Prime Minister. It is his call as to which portfolio is responsible for which piece of legislation and in that case—given you ask where our role is—it is not Finance's role to allocate. But once legislation is allocated to a particular department, with that legislation comes all of the responsibilities that flow from that in terms of administration, including any special appropriations that are contained within it, which goes to some extent to the discussion we had earlier regarding mirror taxes and the Attorney-General's Department.

Ms GRIERSON—The Audit Office identified 12 entities that had been making refunds of taxes, levies and charges without disclosing those refunds as a use of relevant special appropriations. They amounted to $1.25 billion. I think the biggest offender was Customs, whose representatives are not here, but there was a recommendation that that be looked at and tidied up. Audit Office, do you know if new procedures have been put in place? Have you had the opportunity to find out? As we have the ATO and Attorney-General's here, they might like to answer for themselves.

Mr Boyd—We certainly found that in the 2003-04 financial statements there was a great deal more reporting of the use of the refund appropriation provided by the FMA Act.

Ms GRIERSON—That is an improvement. Attorney-General's and ATO, were you aware that those refunds were not being disclosed as a use of the special appropriations? Have you made changes to that?

Mrs Moody—Certainly we made changes in the 2003-04 financial statements and we got legal advice from the Australian Government Solicitor that confirmed that section 28 of the FMA Act was the appropriate power under which to make those refunds. That is now reported as such in note 25(c) of the ATO's annual financial statements.

Mr Kennedy—We have similarly made changes to our process to ensure that they are properly recorded.

Ms GRIERSON—It is good to hear of that improvement.

CHAIR—As there are no further questions from members of the committee, I thank each and every one of you for appearing today. I really look forward to our budget in May when we will see all these accurate reports and amounts put forward with no deviation from where the special appropriation should be spent.

Ms GRIERSON—I hope you will not mind if we ring you all up just to get things clarified when we are trying to read those portfolio statements.

Senator HOGG—Witnesses, please leave your names and addresses.

Proceedings suspended from 12.14 p.m. to 1.30 p.m.

COCHRANE, Mr Warren John, Group Executive Director, Australian National Audit Office

GREENSLADE, Mr Alan Jeffrey, Executive Director, Australian National Audit Office

HALTON, Ms Sarah Jane, Secretary, Department of Health and Ageing

LAW, Mr Alan, Chief Operating Officer, Business Group, Department of Health and Ageing

LEARMONTH, Mr David, First Assistant Secretary, Primary Care Division, Department of Health and Ageing

McEWEN, Dr John, Principal Medical Adviser, Therapeutic Goods Administration

MEERT, Mr John, Group Executive Director, Australian National Audit Office

NICOLL, Ms Gillian, Senior Director, Australian National Audit Office

SLATER, Mr Terry, National Manager, Therapeutic Goods Administration

STEVENSON, Mr Jim, Senior Director, Performance Audit Services Group, Australian National Audit Office

CHAIR—I reopen today's public hearing, which is one of a series of hearings to examine a report tabled by the Auditor-General in the second quarter of the 2004-05 financial year. This afternoon we will be taking evidence on Audit report No. 18 2004-05: *Regulation of non-prescription medicinal products*. I welcome witnesses from the Australian National Audit Office, the Department of Health and Ageing and the Therapeutic Goods Administration to provide evidence on Audit report No. 18. I remind witnesses that the hearings today are legal proceedings of the parliament and warrant the same respect as proceedings of the House itself. The giving of false or misleading evidence is a serious matter and may be regarded as a contempt of parliament. The evidence given today will be recorded by Hansard and will attract parliamentary privilege.

Today's session will be a roundtable format with witnesses from the three agencies appearing together. However, I ask participants to remember that only members of the committee can put questions to witnesses if this hearing is to constitute formal proceedings of the parliament and attract parliamentary privilege. If other participants wish to raise issues for discussion I would ask them to direct their comments to the committee. It will not be possible for participants to respond to each other directly. Secondly, given the short time available today, statements and comments by witnesses should be relevant and succinct. I ask each of you to make a brief opening statement to the committee.

Ms Halton—I note that Senator Moore was in estimates when the question of the audit was canvassed so some of us will be going over old ground for her and I apologise to Senator Moore.

In essence, we found the ANAO audit process to be a very useful exercise and we would like to acknowledge that it is making a very constructive contribution to the ongoing improvement of the TGA's procedures. I think it is acknowledged that the TGA is one the world's leaders in the regulation of therapeutic goods, and it is our continuing ambition to strengthen the TGA's governance and operations to ensure that it remains at the forefront.

You would be aware that we have accepted all of the audit recommendations and the department is currently in the process of progressing their implementation. I have established an audit subcommittee, which is why Mr Learmonth is with us today, to oversee and report to me on the implementation of all of the recommendations. This subcommittee will also advise me on any additional improvements that may be warranted in relation to the TGA's administration that go beyond the specifics of the ANAO audit.

In order to progress that work the subcommittee is in the process, as we speak, of engaging a consultant to assist with the work. We are going to ask the person or persons to assist the TGA in implementing the ANAO recommendations, including developing an implementation strategy; to undertake a review of recent key enforcement actions by that TGA to draw lessons for the future—that is particularly in line with recommendation 13 of the report; and to take an overarching view of the TGA's governance frameworks and make any recommendations that they consider to be appropriate and necessary.

As I have mentioned, the consultant will report to the subcommittee of the audit committee on these tasks and advise on the sufficiency of the work undertaken by the TGA in order to meet all of the ANAO's recommendations. The consultant will also provide the committee with comments and recommendations on broader matters, as I have already indicated, in respect of the TGA's regulatory and governance frameworks. I might add that we will think about those more broadly across the Health and Ageing portfolio because we have a number of regulatory roles in the portfolio. The department is currently assessing responses from the market for those consultancy services and I hope the consultant will commence work in mid-April, with the bulk of the work being completed mid-year. We are here to answer any questions that the committee has.

CHAIR—Does the Therapeutic Goods Administration wish to make any comments?

Mr Slater—No, Chair.

CHAIR—Does the Audit Office wish to make any comments?

Mr Cochrane—Let me start by thanking Ms Halton for acknowledging the worth of the audit report. Beyond that, I will let the report talk for itself.

CHAIR—You had me thrown there for a moment, Mr Cochrane—I thought we were going to get another report! I might ask a blatantly obvious question: what is an audit, in relation to the TGA, in non-prescription medicinal products?

Ms Halton—Maybe you should ask the Audit Office.

CHAIR—No, I mean: what is the audit that you carry out?

Ms Halton—I see—you mean that sort of audit. I beg your pardon.

Mr Slater—We inspect manufacturers of therapeutic goods to the code of GMP—good manufacturing practice. The code is an internationally derived code from the European Pharmaceutical Inspection Convention, so Australia harmonises with Europe on this model. We therefore schedule audits in the one- to three-year category to ensure that we inspect manufacturers on a regular basis according to the code. We risk assess those manufacturers to determine the frequency of audit, and in the planning before we audit a manufacturer we look at audit history, at adverse drug reactions and at intelligence that might have come our way from complaints or from problem reports relating to product quality. On that basis we target aspects of the manufacturer that we wish to assess on that particular audit.

CHAIR—Do you do separate audits to check the quality of the product?

Mr Slater—Besides the audit, which is about ensuring that quality is built into the system for producing therapeutic goods, we have a process of randomly testing products to ensure that they are of adequate quality, that they contain the active ingredients and that they are what they say they are.

CHAIR—How do you determine how long it is between audits?

Mr Slater—As I said, we determine that on the basis of previous audit history and on the risk of the product. If it is a prescription medicine which requires high levels of sterility, for example, it is in a high-risk category compared to a herbal product where the ingredients that are being used are safe. Those are the extremes of the risk framework. So we work on that basis plus previous audit history, reports from random tests, reports of adverse drug reactions and intelligence that we might have.

CHAIR—Are your audits announced before they take place?

Mr Slater—In the majority of cases they are. The basis for that is that we recognise that, if we are auditing on whatever frequency, the moment we leave the manufacturer the objective is to build quality into the system—to ensure that the processes and procedures are such that quality will be maintained, rather than having a snapshot, if you like, that they are meeting their manufacturing commitments at that particular point in time. Where we have intelligence or where there is a suspicion that practices and the code are not being followed we will undertake an unannounced audit.

CHAIR—In relation to Australian audits, how many staff do you have that do non-prescription medicine manufacture audits?

Mr Slater—That is not easy to answer, because most manufacturers do a mix of therapeutic goods. They will have non-prescription medicines and prescription medicines in a large number of cases, and non-prescription medicines and medical devices or other therapeutic goods in other cases. So to say what is exclusively non-prescription is a question—

CHAIR—If you were to ballpark it, how many staff would you have? What percentage of their time do they attribute to it?

Mr Slater—Altogether we have 26 auditors that are dedicated to auditing manufacturing facilities. But they also have available to them specialist auditors in the areas of, say, blood and tissues and there might be laboratory or IT specialist staff who come and look at a procedure. So that could increase the number of people involved to up to 40 or 50, but I would have to take that question on notice.

CHAIR—Are those people also doing the overseas audits?

Mr Slater—Yes.

CHAIR—So that is overall?

Mr Slater—Yes.

CHAIR—Do you have more staff doing audits now—in 2003: in this report—than you did in 1999?

Mr Slater—Yes.

CHAIR—Then why is it that you did 105 audits in 1999 and 70 audits in 2003? If we include the overseas ones, you did 140 audits in 1999 and in 2003 you only did 93.

Mr Slater—Those figures are not familiar to me but—

CHAIR—They are on page 50 of the auditor's report. What I observe as I look at the table on that page is that, even though you have stated that the number of audit staff that you have has increased, the actual number of audits, whether they be licence, routine, special, overseas or Australian, has reduced.

Mr Slater—The answer about the number of auditors having increased since 1999 is that, firstly, in the last 18 months—we are in April 2005 now—we have doubled our audit staff. We have brought to bear, if you like, as the figures for the last half of 2003 show, an additional number of auditors. The second reason is that in 2003, following the Pan Pharmaceuticals audit, we had a lot of tip-offs and intelligence, which disrupted our normal audit program. Thirdly, in overseas programs, we ran into SARS and into some enforcement—

CHAIR—But weren't they all post 2003? What year was Pan in?

Mr Slater—Pan was in 2003.

CHAIR—And SARS was in 2003?

Mr Slater—Yes, 2003-04.

CHAIR—This report only goes to 2003.

Mr Slater—I was just going on to say that there is the enforcement action from the war on terror.

CHAIR—If you have a look at the table I referred you to earlier you will see that your numbers dropped off in 2000, in 2001, in 2002 and yet again in 2003.

Mr Slater—This is a list of non-prescription medicine manufacturers. There are device manufacturers and there are prescription medicine manufacturers, so you would have to bring together the totality to get the true picture of that.

CHAIR—I accept that. We would perhaps like those figures presented to this committee so that we can get a better understanding of the whole picture—accepting that the audit was into the non-prescription medicinal products.

Senator WATSON—Was there a decline in compliance in terms of these figures that you are referring to, or was this the result of a changed Therapeutic Goods Administration approach?

Mr Slater—We had a new code of GMP which came into effect in the period 2002-03, so there were changes to the code.

Senator WATSON—What did that say?

Mr Slater—It brings in certain aspects of the code. In line with international standards, it introduced new aspects to good manufacturing practice that manufacturers had to comply with. We would have audited it too. There was a period of transition for those companies to move to the new code. For that transition period we had to administer both codes.

Senator WATSON—Wouldn't that have increased your audit activity rather than decreased it?

Mr Slater—No, it increased the complexity in the sense that we had to ensure that they were adhering to either one or other of both the codes.

CHAIR—How often are your overseas certified companies audited?

Mr Slater—On the same basis as Australian manufacturers.

CHAIR—Is it determined by the review panel?

Mr Slater—No, the frequency is determined by the risk management strategy that I alluded to earlier for domestic manufacturers. It is a similar risk profile for overseas manufacturers.

CHAIR—How do you determine the quality of that matrix in relation to going back and doing the time frame between audits?

Mr Slater—On the same basis—that is, the level of compliance with previous audits, the results of adverse drug reaction reports that we might have in Australia, the results of random

testing that we would have done on those products, any intelligence or complaints that we might have received and any problem reports that we received.

CHAIR—Do you have any documentation that supports the development of the matrix and the timing frequency?

Mr Slater—Yes, there is a standard operating procedure that outlines that.

CHAIR—The audit report says in paragraph 3.6:

The rationale for assigning the specific audit frequencies for given risk parameters has not been documented.

Mr Slater—Certainly in the latest standard operating procedure any concerns that the Auditor-General raised in relation to those audit frequency parameters are documented.

Ms Halton—If I can go back to those opening remarks, one of the things we will do with this consultant that we have employed is a thorough examination of each of these recommendations in order to make sure that there is a one-on-one match with the recommendations coming out of here and processes and procedures.

CHAIR—Will you report back to this committee on the progress of your actions on those recommendations?

Ms Halton—We would be very happy to.

CHAIR—Thank you very much. The audit report in that same paragraph, 3.6, says that the:

... systematic risk analysis has not been undertaken in support of the audit frequency matrix, nor has the matrix been evaluated since its introduction.

This is the report tabled by the Auditor-General, obviously after auditing your department. It also says:

The TGA's information systems do not contain some of the information necessary to do such analyses.

Mr Slater—Certainly we are having a look at the matrix as a result of this audit. That matrix says we have determined audit frequency to be divided into a three-tiered structure, or a three-tiered matrix, of high risk, medium risk and low risk. We have not changed that, as noted by the ANAO. It has served us well, but we are having a look at it to see if it can be improved.

Ms Halton—I might ask Mr Learmonth to read you some of the terms of reference for the consultant that we have got on the market.

CHAIR—You can read them, but you can also submit them as a submission.

Ms Halton—I am happy to table them if you would prefer that. It is explicitly covered.

CHAIR—I will hear them and then you can table them as a submission.

Mr Learmonth—The relevant element of the terms of reference is:

Particular emphasis will be in the following areas—

amongst others—

- reviewing and enhancing the TGA's risk management framework;
- development and implementation of an appropriate performance management system; ...

So the consultancy is very much focused on that question.

CHAIR—Would you be able to table the whole of the terms of reference for appointing a consultant to go through these?

Ms Halton—Yes, we are very happy to.

CHAIR—Will you send those as a submission after the hearing or do you want to table them now?

Ms Halton—We will table them now, if you like. It might be easiest.

CHAIR—The thing that comes to mind as I read through the audit report—and I respect the fact that perhaps some of the people here were not here during the processes in earlier times—is that the TGA seems to have been more in a reactive mode than a proactive mode in its audit process and in seeking out issues of concern with quality management. I will let you respond to that first, then I will come to the next question.

Mr Slater—I think the focus of individual auditors has always been on ensuring that there is compliance with the code of good manufacturing practice and hence that focus is entirely about ensuring that there is a good quality outcome. I think we might draw a line about being reactive as post the Pan Pharmaceuticals audit. We had a large number of complaints from other manufacturers, from staff employed by those manufacturers, from, if you like, competitors and from consumers about concerns that they may have had about adverse drug reactions, which meant that we were certainly reactive to those things. That is very much part of the framework that we have in responding to concerns that might be raised about the quality of therapeutic goods.

CHAIR—So would it be fair to assume that your charter or your mission statement would be about assuring that quality health products are available on the market?

Mr Slater—Yes, that is certainly part of our mission.

CHAIR—Then I ask the question: why did the GMP audit unit cease its ISO 9000—which is the international protocol on quality assurance—and National Association of Testing Authorities accreditations in 2003?

Mr Slater—We were outstanding in the fact that we had an external certifier, NATA, to give us external accreditation to an external quality standard. Following recommendations from previous audits and from internal audits, we had a consultant undertake a review of our GMP area. The consultant concluded that the external accreditation was of little value, that TGA's own internal procedures were robust and that the quality system we had in place was providing better value, in their opinion, than the external accreditation. As a result, we introduced a quality systems manager to oversight maintaining the level of quality. However, as a result of the issues that have been raised by the ANAO, we are seeking accreditation again from NATA for reaccrediting us to an external standard.

CHAIR—As I understand it, at this point in time you have no international or national quality assurance rating.

Mr Slater—External certification.

CHAIR—Under ISO, or none?

Mr Slater—We had ISO. We will now resume accreditation to ISO, but we have been belonging to PIC/S. We were inspected by PIC/S in—

CHAIR—Sorry, who is PIC/S?

Mr Slater—That is the European Pharmaceutical Inspection Convention that we belong to, which is the group of countries which have recognised each other's skills in the area of GMP. They audited us in July 2003. WHO has audited the TGA's GMP processes. Both of them regard the TGA as a world leader in GMP quality.

Mr Learmonth—I can certainly set out the historical perspective, but we are aware that the industry has raised concerns about ISO accreditation. We would expect that to be one of the areas that the consultant would revisit as part of their work.

CHAIR—I ask the Audit Office: is it unusual for a regulatory authority not to follow ISO or some similar international quality standards?

Mr Cochrane—I would have to take that on notice. We have looked at a number of agencies, but they vary across a wide spectrum of activity. I could not say offhand whether they all have ISO accreditation.

Ms Halton—To my certain knowledge, they do not.

CHAIR—If an Australian company were producing a product which it previously produced to ISO 9000 standard under your guidance and then it wished to start to export that product offshore and could not put an ISO 9000 tag or a NATA tag on it, how would that help those companies wishing to enter export markets?

Mr Slater—In the area of medical devices where ISO certification is undertaken, the TGA assesses companies' compliance to the relevant ISO standard. We are accredited to do that, so we

are able to give those certificates. In the area of medicines no-one in the world provides ISO accreditation, to my knowledge.

CHAIR—The report was tabled in the House 12 months ago. You stated that you have commenced practices. I will give you the exact date as I do not want to mislead you.

Ms Halton—It was 16 December 2004, Chair.

CHAIR—Yes; sorry, it was last year. You said you had now engaged, as a result of the audit, a consultant to look at the issues pertaining to accreditation. You have got a consultant looking at the issues of audit. What other areas is the consultant looking at?

Mr Learmonth—The consultant is about to be engaged—tenders closed last week—but there is a consultant who will be taking an overarching look at the whole of TGA's operations. They will be using the ANAO report as a springboard. They will certainly be reviewing the work that has already been undertaken by TGA to respond to the recommendations. They will be looking to see whether or not the responses undertaken and planned can be enhanced. They will be looking more broadly at the organisational governance and procedural framework of TGA, in particular its risk management and performance management systems, so it is the full gamut of the operation.

CHAIR—Is it the wish of the committee that the undated submission from the Department of Health and Ageing received today be accepted as evidence by the Joint Committee of Public Accounts and Audit's sectional review committee of Auditor-General's reports and be authorised for publication? There being no objection, it is so resolved. I refer to the issue of your audit frequency and your audits due. From what I understand, 40 per cent of manufacturers audits are behind schedule.

Mr Slater—As of today there are no audits overdue. There are audits that are in the category of 'zero to six months', which the TGA does not classify as overdue. 'zero to six months' gives us a period in which to ensure that, where appropriate, group audits are done. For example, just because it is dated 22 April and the next one is due on 24 May you would wait and do it on 24 May or bring it forward to 22 April, so for sensible scheduling purposes we start to consider them overdue after six months. There are no domestic audits overdue as of 5 April and there are no overseas audits overdue as at 5 April.

Senator HOGG—Sorry, what does 'overdue' mean?

Mr Slater—Anything that is beyond six months.

CHAIR—Simply rescheduling them does not dismiss the requirement for an audit.

Mr Slater—We have audited these companies and none is beyond six months past their due date of audit.

Senator HOGG—I hear what you say about not being overdue within 'zero to six months', but I personally do not work by that standard, nor can I cop that as a standard. I can understand the argument that you put forward in terms of scheduling—that you might delay one and bring

another forward—but I think your 'zero to six months' is just a little bit out of kilter. Let us go to the audit committee. I presume you have an internal audit committee. Is there a separate internal audit committee for the TGA or is it part of the Department of Health and Ageing?

Ms Halton—It is part of the Department of Health and Ageing.

Senator HOGG—Do you see a need for a separate internal audit committee for TGA, given the results? I know you are addressing the outcome of the Audit Office report but, given the outcome, do you see a need for an internal audit group within TGA?

Ms Halton—I am going to take advice from the consultant on governance more broadly, and I think I have already indicated that. I have to say my initial leaning is no. Having things at more distance means they are less visible and having them closer in makes them more visible. But the reason we have established a thoroughgoing review not just of the contents of this report but of governance more broadly, as Mr Learmonth has indicated, is precisely to enable us to consider those kinds of questions. What would be the optimal governance arrangement? What is the optimal level of oversight in terms of connectedness into the department's audit committee et cetera? I think it is probably not sensible to prejudge the consultant's work, but I do have a view that the department's committee should be responsible for all aspects of the department's operations.

Senator HOGG—I hear what you say, but I am not necessarily prejudging the work of the consultant. I have been on this committee on and off now for quite a substantial period of time and I have seen a large number of audit reports reviewed by the sectional committee, and I cannot say I have seen one which reflects as badly on an agency or a department as this did at that stage. I accept that you have taken remedial action in its wake. That is why I am surprised that you have not seen the necessity straight off to put in place some form of internal audit committee within the TGA. Having 26 recommendations from the Audit Office in an audit report is really quite extraordinary indeed. I used to think Defence were bad, but let me say that you make Defence look like a bunch of pussy cats.

Ms Halton—I find that a fairly extreme statement. The simple reality is—

Senator HOGG—I am entitled to make an extreme statement.

Ms Halton—You can make that statement, but I would have to make the observation that my accounts have not been qualified, unlike the defence department's.

Senator HOGG—That is a fair enough statement, but we are talking now about a range of issues. There are 26 recommendations from the Audit Office—

Ms Halton—Correct.

Senator HOGG—which your department have picked up—and rightly so—and have agreed to implement. I am looking at what I think is a fair statement. I asked why an internal audit committee has not been established simply for the TGA, given that I have not seen an Audit Office report of this nature—and I think you have answered that.

Ms Halton—And what I have also said is that I have actually got an audit subcommittee which is examining this issue explicitly.

Senator HOGG—Yes, I accept that.

Ms Halton—So there is an audit committee governing the whole operation of the audit function, and we have established a subcommittee of the audit committee to undertake this particular task. In my judgment, a completely separate committee in fact serves to be disconnected from the audit function more broadly. It is likely going to contain the same people in any event, but to have it as a subcommittee of the audit committee connects it properly in a governance sense, in my view, to the audit function. But it is getting sufficient treatment from a dedicated group of people looking at the issue.

Senator HOGG—On that audit subcommittee that you have established, how many members are out of the TGA area?

Mr Learmonth—One.

Senator HOGG—And who would that be?

Ms Halton—Mr Slater.

Mr Learmonth—That would be Mr Slater. The others are Mr Law and me.

Senator HOGG—What independent people are there on the subcommittee? Any?

Ms Halton—There is an independent member on the audit committee who is oversighting the operation of this activity.

Mr Learmonth—I think the way we imagine this would pan out is that the short-term focus of this audit subcommittee is to manage the consultancy, to manage the implementation of the ANAO's response and to look more broadly at what ought be done with the TGA in terms of how it operates, how it is governed and so on. What that audit committee might become as a result of that consultant's work and advice on governance is another question, as the secretary has outlined. So that is our short-term focus at the moment. What it becomes when we get the consultant's report and when the secretary has had a chance to consider our advice and the view of the consultant might be another matter.

Ms Halton—The audit committee does contain an independent member and has done for many years. The independent member takes her duties very seriously and talks to me about operations of the audit committee. As this is a subcommittee of the audit committee, there is that level of independent scrutiny.

Senator HOGG—Has your own internal audit committee expressed any concerns about the outcome of the report, or were they expressing concerns prior to the ANAO report about the operation of the TGA?

Ms Halton—I think we need to put this in context. The reality is, as Mr Slater has indicated, that the TGA is internationally certified in terms of its reciprocal arrangements with the Europeans. There are very few countries that have achieved the status that the TGA has. That said, it is always possible to improve and that is precisely why we welcome the audit as being very timely—to improve the way we regulate. The reality is, if you look at areas right across government, how we used to regulate five or 10 years ago is now considered outmoded. In terms of regulation, even in other parts of the portfolio like aged care, we have learned and moved forward. This exercise was, in fact, highly timely. Yes, the issue of TGA operations has been discussed in the audit committee—and Mr Law might choose to speak to this. Alan, do you want to provide some detail?

Senator HOGG—I thank you for your answer but I am looking at the time prior to the commencement of this audit by the ANAO, who are external to your agency. I think that is probably one of the reasons why the audit is as rigorous and as far-reaching in the recommendations that have been made to you. Did your own internal audit committee pick up on the range of issues that the ANAO did and, if not, why not?

Mr Law—I would like to clarify one issue. The TGA is part of the department; it is not a separate agency of the department.

Senator HOGG—I understand that. I might be seen to be splitting hairs here.

Mr Law—The scrutiny of the audit committee, as a whole, covers financial auditing on an annual basis. There is significant scrutiny of the financial audit reports which are separate from TGA. That does go into issues of controls within the overall framework. Also, TGA is included as part of the overall audit program of the department. From an internal audit point of view, TGA is included in terms of the scheduling of internal audit. I cannot speak here about exactly what those internal audits have been over the last couple of years in terms of the overall schedule, but it is part of the internal audit scrutiny of the department. In terms of the specific issues that the ANAO has raised, I cannot say that those issues were things that have come to the attention of the audit committee from separate sources. There are a range of other issues that are presented to the audit committee as part of the audit program.

Senator HOGG—I will tell you what my concern is—unfortunately, I now have another commitment that I have to go to. I worry about the role of internal audit committees within departments, agencies or whatever they may be. I do not know how rigorous or how exacting they are on their own internal processes in identifying the issues that were raised here. My question goes to the effectiveness of your own internal audit committee system which would see the ANAO, with their expertise in doing audit, step in independently. Why didn't your own internal audit committee pick up on these issues themselves? I could understand the ANAO coming in and finding a range of issues but not anything as comprehensive as what seemed to have come about in the TGA report.

Ms Halton—I would like to make a comment about that. The reality is that my audit people worked in partnership with the ANAO. We regard this as being an opportunity, not a threat.

Senator HOGG—I accept that.

Ms Halton—I think your question about audit committees is actually a very fair question. One of the strategies I employ involves seeing the program from the ANAO come round. Very often, they will bring a level of independence and scrutiny. I will make a decision, quite tactically sometimes, to have the ANAO look at a particular issue, then I might deploy our internal people in another way. There is no point in duplicating.

Senator HOGG—I am not after duplication.

Ms Halton—Exactly.

Senator HOGG—All I am saying is that it seems that, with the diverse range of recommendations that have come out of the ANAO, if your own internal audit arrangements were working well, you would have identified a number of the issues here earlier rather than relying simply and solely on the ANAO. I am sorry, but I have to go another meeting.

Ms Halton—I would want to if we had more time.

Senator HOGG—I will be back.

CHAIR—On the issue of using the Audit Office to come in and do the audit—and I might direct my question through the Audit Office—how is the relationship there?

Mr Meert—The relationship with the department has been very good. I will put it on record that the secretary has been very positive in responding to all the recommendations and assisting us on the report and conducting the audit. It has been very positive in general, even on the audit committee.

CHAIR—Was there any reluctance at all in providing information to the Audit Office during its inquiry between September 2003 and October 2004?

Mr Meert—There was a degree of reluctance from TGA.

CHAIR—Over what issues and what areas did that reluctance manifest itself?

Mr Meert—It just meant the time frame for the audit was extended.

CHAIR—What was the initial time frame required for the audit?

Mr Meert—I think, from memory, it was scheduled to take 11 months.

CHAIR—And it took 13?

Mr Greenslade—I think it ran about four or five months late.

Senator WATSON—I have two questions. In terms of the outstanding audit activity, you state that as of today there are no overdue audits, recognising the six-monthly interval. What is the

intended starting date of the audit? Is it the date of the original scheduling or is it the rescheduled date?

Mr Slater—The standard operating procedure for audit frequency is that the audits are to be conducted within a six-month period from the due date.

Senator WATSON—My question is: what is the due date? Is the due date the original date or the rescheduled date? In one of your answers you had us confused, because you said you have gone through and rescheduled all your audit activities. So my logical question was: what is the due date? Is it the original date or the date from the rescheduling?

Mr Slater—I am sorry if I confused the committee. The due date is the date that the next audit is due.

Senator WATSON—But you still have not answered my question, with respect.

Mr Slater—Let me be clear—there are no audits that are over six months due past the original date set for the audit.

Senator WATSON—The date that was originally set for the audit, not from the rescheduled setting. Can you assure the committee of that?

Mr Slater—I am sorry if I used the word rescheduled. I am not quite sure in what context I used it.

Senator WATSON—You said the original scheduled date.

Mr Slater—We have cleared the backlog, in other words.

Senator MOORE—Is that on a calendar year or a financial year basis? By that I mean January to December.

Mr Slater—That is on a calendar year basis.

Senator WATSON—In relation to the charter of good manufacturing practice, how many serious adverse reports or warnings have you issued in the past four years?

Mr Slater—I could not give you an answer off the top of my head on what are called critical deficiencies.

Ms Halton—Are you talking about non-prescription or all products?

CHAIR—We will stay on non-prescription products.

Mr Slater—I would not have that detail.

Ms Halton—We will provide that.

Senator WATSON—Would it be many?

Mr Slater—There have been a number.

Senator WATSON—Five, 10 or 50?

Mr Slater—No, there would have been more than a dozen.

CHAIR—Would it be fair to say that 20 per cent identified a potential risk to health?

Mr Slater—Yes, that is right.

Senator WATSON—How seriously would you regard the following: no cleaning procedures for cleaning, for example, the wash bays; cleaning cloths and sponges on floors directly under the outlets from sinks; cleaning brushes used for cleaning nozzles covered in extraneous material; cracks in walls and ceilings and rooms not clean; tubing to pumps that supply coatings stored in dirty and damaged boxes; hot air equipment covered with dust and not appearing to be clean; puddles on floors; and loose covers in mixing rooms, which wind lifted, exposing surfaces that appeared soiled and dusty? Do you regard those sorts of issues as serious?

Mr Slater—Yes.

Senator WATSON—Would they warrant a special report?

Mr Slater—Indeed.

Senator WATSON—Could you give the committee copies of what you regard as the serious reports?

Mr Slater—Certainly.

Senator WATSON—I think people reading these sorts of things would be alarmed about preparations prepared in these sorts of conditions.

Mr Slater—Absolutely. I would agree with you.

CHAIR—So you will take that on notice and provide the information to the committee.

Senator MOORE—I wanted to ask about record keeping. I am wondering whether this is the right time.

CHAIR—Yes, that is fine.

Senator MOORE—One of the things that tended to come up regularly in the ANAO report was concern about what was kept on record and what was easily obtained. I know that you were putting a special subcommittee together to look at it. Is the IT system and the way the IT system is used and maintained one of the key components of that?

Mr Slater—We have set out over the last eight years to completely redesign and regenerate the TGA's IT system.

Senator MOORE—You have spoken at Senate estimates before about that process.

Mr Slater—That is coming to a conclusion. The last elements of that are going through now. Certainly it was one of the frustrating points for the ANAO that we relied on paper file records for our information, and they took extracts from databases that we had to assist us rather than being the repository of the data that we used. Record keeping is a big issue for us. With those IT systems coming on line we will be in a situation to get far better reporting of any issues that management might require to pay attention to, plus, if you like, the routine management of programs.

Ms Halton—Could I add to that. I will want the consultant to give me advice as to whether those systems in fact adequately address the issues that arose in the audit and, as I have already indicated, in a sense go beyond the scope of the audit, looking forward to where we want to be in however many years time.

Senator MOORE—One of the things that came up was that, when looking at a manufacturer's record or a product, it was difficult to see what had gone before. I know the upgrade of the system never ends—it just goes on—but is there going to be the capability to have historical data entry? You cannot really draw a line and say it will be from this day forward unless you have some kind of fall-back. With your work, is the idea that you will be able to have your system up to date now with all the changes that have occurred even over the last six to 12 months and be able to look at a major product or a major manufacturer and pick up the kinds of things the ANAO have said they wanted to see quickly? That includes data on previous audits, things that have happened and the time frame—all that kind of data.

Mr Slater—It is the purpose of the information systems design that we have those databases attached to those systems.

Senator MOORE—Can we get some information on that? We have probably had it at Senate estimates but I think that, if we are going to keep a full package, that is one of the key components of what the ANAO asked for—those clear data records.

Mr Slater—Of course, for long-term historical data there will be archival material on the files.

Senator MOORE—And there will be some kind of reference system you have to go and check.

Mr Slater—Yes.

Senator MOORE—I cannot help myself, but they made a particular reference to documents being numbered on the paper file—

Ms Halton—Folioed.

Senator MOORE—which is one of my favourite things. I do not know how you go back and folio it. It is simple things like that which seemed to have caused concern.

Ms Halton—Regrettably, notwithstanding the fact that I keep advocating clerkliness—including the folioing of files—it does not happen as often as one would like.

Ms GRIERSON—Senator Hogg expressed his disappointment in the audit report, and I have to say I found it a very critical audit report in an area that the public are alert to and therefore very interested in and the outcomes of which they perhaps have a particular stake in. I am also concerned about what you have said to me, Mr Learmonth, that the consultant will cover the whole gamut. I wonder if sometimes the consultant's fee would be better paid to the audit office, in that 26 recommendations give a whole framework for operation—a framework that perhaps should have been there in the first place. When we see 26 recommendations, it is usually because processes are not only not being followed but at times are not even in place. To be fair, the audit office said there were frameworks but certainly the processes and practices were not directly linked or were not being followed and that the outcomes were therefore diminished because of that.

I also think the time for the consultant's report is critical. I would think you could delegate operations to the TGA but you cannot delegate complete responsibility to the TGA because the Department of Health and Ageing have set them up to assist the department on their responsibility for the good management of health related practices in this country. So I am very concerned that time will slip further and further out by having a consultant in what I think is perhaps a questionable method to make sure the response to the report is thorough and in place—but I guess those are editorial comments.

Ms Halton—Sorry, I feel it necessary to editorialise back. The reality is that there is not a suggestion in this audit report that there are products on the market in this country which are unsafe.

Ms GRIERSON—Therefore are you willing to give the public of Australia at this hearing today the guarantee that you can assure that all products coming into this country and this market are safe?

Ms Halton—What we can guarantee is this: short of testing every single product that enters the market—and there is no suggestion that this country is going to engage in such a regulatory regime, with the costs that obtain—we have one of the best approaches to monitoring manufacturing and to monitoring negative outcomes for patients and consumers. One of the reasons we pick up potential difficulties fast in this country is precisely because our adverse reaction notification—and John McEwen might want to make a comment about this in a second—is at the forefront in the world. As I have already indicated, there is no doubt that you can always tighten arrangements in any system. That is one of the reasons we were encouraging of the ANAO to be thorough and fulsome—in fact, I said to the ANAO on several occasions through this process: 'I actually want you to give us a complete list of recommendations, not the four or five headlines,' precisely because it assists in the management of this exercise. But in terms of the quality of products on our market—and this goes both to registered pharmaceutical products and to the area of complementaries, which are largely not regulated in other parts of the world—there is no doubt in my mind that we are world leaders.

Ms GRIERSON—I am going to interrupt you there because I do think that time is very short. I would also qualify what you have said by saying I have complete confidence in the audit office to do their report as thoroughly as they have to, no matter what your instruction or cooperation ever was with them. It is their job. It is their duty. They will do it anyway. They understand the importance of their audit reports to us.

Ms Halton—Indeed.

Ms GRIERSON—So I would ask TGA: what is the current status of the audits of overseas manufacturers of non-pharmaceutical medicines at the moment?

Mr Slater—There are no audits overdue—that is, beyond six months.

Ms GRIERSON—Even the overseas ones? You have caught up on those?

Mr Slater—We have caught up on all the programs.

Ms GRIERSON—What about the use of unannounced audits? How often have you applied that strategy in this catch-up phase?

Mr Slater—The major exercise here was to ensure that we completed the audit program that was set in front of us and that there were no outstanding audits. We had audits on the program that were overdue and we have completed those audits to the schedule.

Ms GRIERSON—There has been a great deal of activity, and I congratulate the TGA on that catch-up strategy. Having done that, you must certainly have then put forward some strategic actions that you see as being necessary. Those audits should shape your actions in the future. What would be the priority areas for the TGA to pursue that have come out of that?

Mr Slater—Each manufacturer is a case-by-case situation.

Ms GRIERSON—So you are telling me there is no trend data—that there is no overall picture and that there is nothing that shapes it? You are telling me that it is just one-off with each individual?

Mr Slater—We do somewhere in the vicinity of 300 audits of medicines and devices manufacturers a year. The fact that we had a backlog to catch up on does not mean that there was no trend data and data available to us about those things that we should give priority attention to in auditing any particular manufacturer. To that extent, there has been, if you like, only a marginal gain in terms of new information available.

Ms GRIERSON—So how many unannounced audits did you actually undertake in 2004?

Mr Slater—I would have to get back to you.

Ms GRIERSON—We will take that on notice. The secretary suggested that we have a high level of quality assurance in this industry. We want that to be the outcome; that is the desired outcome. One of the good things, I suppose, is that since Pan Pharmaceuticals there is a higher

degree of awareness. When we look at some of the tampering with pharmaceutical products, we know that the Australian public have a great deal of willingness to provide you with information. Have tip-offs increased? What is the trend in terms of tip-offs? Is that one of the things that fortunately is shaping proactive operations?

Mr Slater—Certainly post Pan Pharmaceuticals we had a large number of tip-offs. I think it is important that the regulator pays attention to any intelligence it gets. Otherwise, you get a situation where complainants stop complaining and the intelligence that is important to underscore the quality of the system falls off. One of the things that the ANAO observed was the frenetic activity that followed Pan as we thoroughly checked out whether Pan was a one-off or whether it was endemic in the industry so that we could assure the Australian government and Australian consumers of the level of compliance and of the level of quality of the products. We frenetically followed up those tip-offs and that intelligence.

CHAIR—I have a question on something that Ms Grierson raised earlier. You said that all your overseas audits are now up to date. How do you justify that there was no audit on China between 1998 and 2004? I see in the report that you try and attribute part of it to SARS.

Mr Slater—There was one Chinese product that was overlooked in that period of time on which we had reports in from the Chinese regulatory agency. While it is not an agency that we would have a mutual recognition arrangement with, that is not to say that they do not thoroughly assess their local manufacturers. They are trying to be accepted by the rest of the world as quality manufacturers. That particular manufacturer produced low risk products that we were not concerned about, so auditing that particular company was low down our list of priorities.

CHAIR—How many products come in from Indonesia? How many companies are there, rather?

Mr Slater—There are a number of manufacturers in Indonesia.

CHAIR—Did you do the audit there in 2003 as you had rescheduled?

Mr Slater—The Indonesian audits have been completed.

CHAIR—In what year?

Mr Slater—In late 2004 and early 2005.

CHAIR—Okay. Their last audit prior to that was 2000. Do you think that time span is acceptable?

Mr Slater—Again, this was a company which, from its previous audit history, we know has a reputation of high compliance. We had great difficulty in travelling into Indonesia. One of the things we try and do in those circumstances to give us some assurance is to get intelligence from overseas regulators that we recognise to see if they have done work in those areas. Then we look to things like adverse drug reactions and so forth to give us assurance about the quality of the products.

ACTING CHAIR (Ms Grierson)—During that catch-up period, have you used any different tools or methods? You have been doing this while the audit has been happening and the audit report recommends the design of many new processes, practices and pro formas to assist you—and standard check lists and support tools for the audit and for the people you audit. In that catch-up period would we have seen any different methods or new tools applied or new processes?

Mr Slater—We accepted the recommendations for improvement in the standard operating procedures around how we conducted audits, and we have implemented those into our procedures. The standard operating procedures that auditors have now incorporate those requirements.

ACTING CHAIR—For the next period would you have a strategy for unannounced audits, for the next 12 months?

Mr Slater—One of the areas for the consultancy review is to try to get a balance in where unannounced audits are appropriate and where the mix, if you like, the balance between announced and unannounced audits, should sit. The ANAO noted that we had a strategy of a high number of unannounced audits in 2003. They were not able to conclude from the material that they had available to them as to whether that added value or otherwise. I think one of the important consultancy focuses is to have a look at the lessons that were learned from that period of enforcement and to make recommendations.

ACTING CHAIR—Were the unannounced audits you have conducted linked to deficiency reports? Were they random? Were they linked to the product itself? What were they linked to? What risk factor were you trying to address?

Mr Slater—If we had an intelligence report—for example, from an employee—that, hypothetically, a machine had failed and was dripping oil into a mix of tablets or that metal contamination was occurring with a product because the machine was shattering, we would do an unannounced audit immediately to investigate those sorts of complaints.

ACTING CHAIR—If you were thinking about your strategy for the future before our consultant shapes that further, what risk factor do you think you would use besides tip-offs of an immediate concern? Besides you being aware of an absolute potential immediate risk from some good citizen or good worker, what other risk factors would you use to determine when you might apply an unannounced audit?

Mr Slater—If we have reports on adverse drug reactions, for example, or, as part of our random testing of products if it were shown that the quality of those products—

ACTING CHAIR—They are very reactive, aren't they? That is my concern. You are reacting to an event that has occurred.

Ms Halton—My view—and this is what I am expecting the consultant to come forward with—is that you have, in the framework for managing your unannounced audits, a combination of the factors we have just talked about, which are the adventitious things, but then you also have a very clear view of what indicators suggest are a greater risk.

ACTING CHAIR—I would hope so.

Ms Halton—Indeed. So, to the extent that we know there is a relationship between—it might be a change in the plant manager; I do not know what the factors will be; we expect the consultant to have a look at these things for us. What are the things that, if you see a constellation of them, even though there has been no adventitious tip-off, would lead you to think they have a much higher chance of getting an unannounced audit?

ACTING CHAIR—The fact that I have had to ask and that you have had to answer is concerning about risk management practices and the understanding of risk management practices.

Ms Halton—Precisely, as I have indicated, the expectation is that in targeting unannounced audits they are not just spread on an equal chance basis across the manufacturers in the sector. A limited resource needs to be targeted at the areas of potentially greatest risk, and we need the indicators of potential greatest risk. I have already just gone to some of the things that may be germane, but the consultant will give us recommendations about exactly those issues. What things do we know from history? The reality is that the expertise is there. People do know these things. But how do we codify that in a way that actually ensures that our targeted program is exactly that?

ACTING CHAIR—Can you give us a picture of the deficiencies of the outcomes over the last 12 months? Are there any deficiencies you have had to register from the audits you have done?

Mr Slater—Yes.

ACTING CHAIR—If you could classify them as onshore and offshore, that would be interesting too.

Mr Slater—There is a full range of deficiencies, from what we will call critical deficiencies, where there are public health and safety aspects which require immediate response from the regulator—

ACTING CHAIR—In the last 12 months, have there been any critical deficiencies onshore or offshore?

Mr Slater—Onshore and offshore.

ACTING CHAIR—There have been both?

Mr Slater—Yes.

ACTING CHAIR—What was the incidence level?

Mr Slater—Percentage wise, again, I would have to go back and look at the data.

ACTING CHAIR—Is it higher than usual? Is it lower than usual? Are we maintaining the same deficiency level in the industry?

Mr Slater—Altogether, there is a level of noncompliance that we detect through our audits. In the last year, that level of critical deficiency has not been any higher than in any other period. We are talking about a large number of audits here—more than 300—so I need to go back and have a look at the data to get percentage trends on that.

ACTING CHAIR—Yes, it is really important that the data is collected and managed so that it can be analysed well. I thought the therapeutic goods industry responded to the Pan Pharmaceuticals incident very well. They put a lot of energy and resources into marketing themselves better, into distancing themselves almost from that debacle, and into assuring the public that the whole industry was not like that. Are you working with the industry in this phase? When you get a critical audit report, the industry knows that. Has there been any attempt to pull those together with TGA to talk about better ways ahead?

Mr Slater—Yes. We have arranged in association with the industry a number of workshops that our experts have attended. We have given training sessions and seminars and generally exchanged information within industry participants particularly in Australia and New Zealand to ensure that the lessons that flowed out of the Pan audit, and the information and the areas that we were concerned about in terms of compliance, were known and that individuals had a good knowledge of their responsibilities.

ACTING CHAIR—If you were trying to get a higher level of consistency across the industry, and good manufacturing practice, what would be three key areas that you might tell the industry that they need to respond to so as to get that standard up?

Mr Slater—The first critical thing is to ensure the inputs that go into a product are of the required quantity and quality. Second, their processes need to be documented and they need the skilled staff and equipment necessary to ensure that production of the product is compliant with the code of good manufacturing practice—that includes ensuring that the employees are trained. Third, their products must be end tested to ensure that the quantities of active ingredients are there, that they are in the quantities required and that the product complies with the end product standards.

ACTING CHAIR—Would you add anything to that to outline current practices which are aimed at ensuring the consistency in auditing?

Mr Slater—The audit focus is to ensure those three critical things are undertaken by the manufacturer.

ACTING CHAIR—Can you assure me that every manufacturer gets a consistent audit, that the same thing happens to them?

Mr Slater—As I said to you previously, when we do the planning for an audit we go back and have look at the history of compliance in those areas that we might have had previous concerns about. We have a look at whether there are any recalls, whether there are any product complaints or whether there are any adverse reactions, which might mean we target particular product areas.

Some manufacturers produce an enormous number of products that range from non-sterile products, which use very low-risk ingredients, to vaccine production, where the level of compliance is a very exacting one. So the focus of the audit would be quite different depending on what product is being manufactured.

ACTING CHAIR—If I were a manufacturer, I would want to know the whole picture—that is, what everyone is being measured against. Yes, I would want to know my individual picture, but I would probably want to know the whole picture. One of ANAO's recommendations was for a more standardised approach to the information in audits. Do you believe that TGA should publish its audit steps and the compliance requirements for manufacturers? Do you think that should be spelt out very clearly for manufacturers? Is there a benefit in that?

Mr Cochrane—I think in most systems where auditing, checking and some sort of assurance is important you need to know what standards you are going to be audited to. Otherwise, as a manufacturer you would not be able to set up your organisation to meet those standards. Certainly if I were a manufacturer I would love to know what standards I was going to be audited against.

ACTING CHAIR—Mr Greenslade and Ms Nicoll, did that come up in individual audits?

Mr Greenslade—Yes, it did. A couple of the recommendations in our report are aimed at improving transparency to manufacturers and getting some of that information out. That is about putting more information out on procedures and on appeals processes and informing manufacturers what their compliance rating is.

ACTING CHAIR—If I had been a manufacturer in this field for the last five years, would I have seen very much different in an audit from TGA? TGA might like to answer that.

Mr Slater—Firstly, to come back to your central point, the TGA does publish the code of good manufacturing practice that manufacturers must comply with.

ACTING CHAIR—Good.

Mr Slater—It is a very detailed code and it is interpreted for the types of products that they manufacture.

Senator MOORE—Is that on the web site, Mr Slater?

Mr Slater—Yes.

Senator MOORE—So people can get to read all of that by looking it up on the web site.

Mr Slater—Yes. That is the standard they have to meet to manufacture therapeutic goods. That is known. In your question earlier, you were getting at how we targeted particular areas of concern that we might have with an individual manufacturer. That is the overlay, if you like, to the systems based audit of their compliance with the code.

ACTING CHAIR—If as a manufacturer I am unhappy with my audit finding, what processes or formal avenues of appeal are available to me?

Mr Slater—The Therapeutic Goods Act provides appeals at four levels. You can ask for an internal review of any decision that might be taken. Prior to that, you can take those issues up with the chief good manufacturing practice auditor.

ACTING CHAIR—By appeal processes, can I delay responding to the audit for very long?

Mr Slater—Where there are critical deficiencies, if they put public health and safety at risk the TGA is able to immediately suspend or cancel a licence. That is what happened in the area of Pan Pharmaceuticals. Where there is not an imminent risk of death, serious illness or serious injury, the TGA has to give a period of notice, which is generally 28 days, of the action it proposes to take. Both of those decisions are appealable. Ultimately, after internal review, the AAT is available for independent review, and then there is of course appeal to the courts.

ACTING CHAIR—Are appeals standard? Is it a standard practice for someone who gets a deficient audit to appeal?

Mr Slater—There is not a large number of appeals.

ACTING CHAIR—Is there a large number of deficient audits?

Mr Slater—Yes.

ACTING CHAIR—That is good.

Mr Slater—In the pre-market assessment area there would probably be a higher rate.

Dr McEwen—I will comment. For there to be an appeal or a request for a review, there needs to be what is known as an initial decision. That means something like suspending the licence or cancelling the licence. In the absence of that, there is not a formalised process by which the sponsor of the product can discuss whether or not it was an appropriation audit. That needs to be taken up, as Mr Slater said, with the chief auditor and perhaps, if one is unhappy, with the national manager of the TGA. It is only where there is a so-called initial decision under the act that the appeal process flows.

ACTING CHAIR—What if I had a deficient finding and I did not want to appeal but I knew I had a particular amount of time to get it fixed up. Could I be very confident that I would get a follow-up audit?

Mr Slater—We require reporting on progress with the implementation of audit findings.

ACTING CHAIR—Would that involve an inspection?

Mr Slater—It could well do. We need objective evidence to satisfy the TGA that that remedial action has been undertaken.

ACTING CHAIR—In what percentage of those times do you think you would do an on-site inspection?

Mr Slater—Where we had any suspicion that the evidence that we had in front of us was not satisfactory to an objective assessment that the work had been done.

ACTING CHAIR—Could you tell me how many times you might do follow-up inspections?

Mr Slater—We have done that. I have to say up front that, following the Pan recall, we found that most of the manufacturers expected to have inspections. It is their brand name, at the end of the day, that they take the biggest risk with in the event that they do not comply with the code. Their reputation can be ruined by a recall.

ACTING CHAIR—I think we understand that, but if you cannot tell me that in 75 per cent of cases you go back and have a look on site—

Mr Slater—I think it is a much lower percentage—

ACTING CHAIR—That is the sort of data that helps us to understand the process.

Mr Slater—Certainly it is much lower than 75 per cent. We do it on occasions where we have any doubt that there is not objective evidence and we certainly follow it up at the next audit.

ACTING CHAIR—I do not mean to be disrespectful, but is there a cosiness and familiarity that may breed contempt in this industry?

Ms Halton—Not according to the complaints I get from the industry.

Senator WATSON—What prosecution action has been taken against the former head of Pan and the senior executives of that company?

Mr Slater—There is a case currently before the court for breaches of the Therapeutic Goods Act which was undertaken in October.

Senator WATSON—October last year?

Mr Slater—That is right. That process is still in train. In that process there is also a matter before the court about the destruction of evidence, which is being pursued under the Crimes Act. Current investigations are continuing into other matters.

Senator WATSON—What about other senior executives?

Mr Slater—As I understand it, the Australian Securities and Investments Commission have matters before the court involving other members of the executive. They are investigating those issues.

Senator WATSON—Could you liaise with ASIC and give us a complete picture of the prosecution action that has been taken?

Ms Halton—I have to say that a large part of this responsibility does not fall within our portfolio. We are happy to give you advice in relation to cases that are relevant to our legislative responsibility, but I think in respect of matters brought by other agencies it is hard for us to be the—

Senator WATSON—But other agencies could raise matters as a result of what you have done or said.

Ms Halton—Sorry, I do not understand the point of your question.

Senator WATSON—Arising from your reports into Pan, obviously other agencies may decide there are other criminal offences to pursue.

Ms Halton—Other agencies may themselves then undertake an investigation, in relation to which they then proceed to take action. I am happy to talk about the action that we are party to, but in terms of other agencies and actions they have taken, if we are not party to them, I am simply saying I think it is difficult for us to provide information about those.

Senator WATSON—For the completeness of the picture I think we would like somehow to get a more global approach. Surely you would be able to liaise with other agencies to assist the committee in this regard.

Ms Halton—We are happy to make informal inquiries. We can give you our best intelligence about what other action is on foot. That would enable the committee to perhaps write to the head of that agency and seek details. We are very happy to do that.

CHAIR—Senator Watson, we will issue an instruction to the secretariat to share that through other means for research, to incorporate it as part of the report—

Ms Halton—And we are happy to tell you informally what we know.

Senator WATSON—Your agency conducts approximately 300 audits per year. Of those 300, in how many cases do you preannounce to the client that you are coming? You have said there are examples—where there is a machine breakdown, loose metal or something like that—where you go in pretty much immediately unannounced.

Mr Slater—The majority of audits that we undertake are announced. That is because of the general principle by which regulators operate around the world. Part of the audit process is to ensure that you pass on to the manufacturer an exchange of information about best practice, that all the key personnel are available and that the environment is right for that exchange of information. That is a critical element of ensuring that the systems in place have quality built into them rather than trying to audit quality into the process. That is the objective and the reason why we do the majority of audits announced.

Senator WATSON—Your presentation today revealed competent, highly professional auditors adhering to the highest of standards. But some manufacturers obviously are not too worried about your visit in terms of the issues that I raised earlier—and they were just a sample of the issues. I would have thought that, if they were expecting an audit, people would make sure that the place was clean and that everything was dinky-di. Obviously, despite your professional and high-standard approach, that does not get conveyed to the clients. Otherwise, people would make sure they had their house in better order in terms of the sorts of things that I raised earlier this afternoon.

Mr Slater—I think it would be fair to say that most companies rate very highly their compliance with the code of good manufacturing practice because, as I have said, they stake their reputation on it. But there are instances—and some of those have been publicly aired as a result of TGA audits—where companies are moving from one premises to another, and they make a deliberate decision to let their premises run down and take the risk that an audit will not take place before they have made that move.

Senator WATSON—The point I am making is that if you were to preannounce your arrival, as the manager of a place, I would make sure that I had everything ticked off to the highest of standards. I am surprised that these sorts of issues can arise at or prior to your arrival.

Mr Slater—Those issues that you talked about, given the amount of notice we give is only a few days, I do not believe could be addressed in that period of time. Some of them may be, but I do not believe the totality of them could.

Ms Halton—I agree with you, Senator, that if you have guests coming you do tend to run around and clean up a bit. It is regrettable that on some occasions when the auditors turn up things are not spic and span, but there is a broader question here, which I think Mr Slater is referring to. The systems and procedures you expect as part of good manufacturing practice should, by definition, generate a clean factory with none of the symptoms that Senator Watson has described.

Senator WATSON—Yes.

Ms Halton—You might be able to go around and do the superficial dusting for the guests, if I can continue the domestic analogy, but very often it would be almost impossible to tidy up all of the things that might be deficient if you are not following GMP, in the two or three days notice that you get. They might be able to tidy up things that are superficial, and you would hope that they did not have to tidy up anything. You would hope that they adhere to GMP and then you could turn up, be it announced or unannounced, and you would see exactly the same thing.

This is exactly why we do these audits: sometimes, as with the Deputy Chair's questions, there are some things which are likely to mean there is more risk with a manufacturer. It may be that they are about to move factory and they have let standards slip. It may be that they have changed their production supervisor to one who does not have the same understanding of or respect for—or whatever it might be—the need to comply with GMP. So we agree with you absolutely: it is not desirable at all and we would hope never to see the sorts of things that you have indicated. But that is exactly why we do go and visit.

Senator WATSON—I have been a factory manager but not doing these things. When I got two or three days or a week's notice that there was going to be some sort of inspection by somebody or some authority, I just issued instructions to every manager or supervisor responsible in the potential areas to make sure that everything was dinky-di, spick and span and working efficiently.

Mr Slater—But if some of the critical systems—such as testing of ingredients in the first instance, laboratory testing to make certain tolerances were being met for ingredient levels, keeping appropriate records, or keeping records of cleaning and so forth—were not being maintained, I do not believe that you could deal with them in the short period of notice.

Ms GRIERSON—Is it possible that, if you got the tick for those one year, you would not look at them the next year? Manufacturers might know what tick-off areas are not a concern.

Mr Slater—I think those particular ones would be pretty obvious.

Ms GRIERSON—Could we move on, then, to the post-market monitoring and testing. Just before we do, ANAO did recommend that manufacturers be aware of their compliance rating. Has that been introduced?

Mr Slater—We have not introduced it. What we have done is consult with the industry about that. We have accepted that recommendation and it will be one of the issues that the consultancy will look at as well.

Ms GRIERSON—So you have not been issuing compliance ratings to anyone yet.

Mr Slater—Not yet. But we certainly have gone out and indicated our intention to introduce that information.

Ms GRIERSON—Have you implemented performance indicators and targets for the timeliness of laboratory testing?

Mr Slater—Yes. We have developed those. Again, they are out for consultation and they will be part of the consultancy study to ensure they meet the appropriate standards of response expected.

Ms GRIERSON—You have a $6.6 million budget for post-market monitoring. Have you any idea how much of that would be for laboratory testing of products and ingredients? It is a fairly cutting-edge type test procedure. I would have though it gives good information.

Mr Slater—The figure that is in my mind is that we spend somewhere in the order of $13 million to $14 million on laboratory services for all of the therapeutic goods products. So it is a significant part of our budget—somewhere in the order of 20 per cent of the TGA's budget.

Ms GRIERSON—Do you agree with the view that perhaps there could be more post-market testing?

Mr Slater—We are not the only ones who have this issue around what is the right quantum: Customs has the same issue in terms of inspection of articles that come into the country. The important thing is how well you target it.

Ms GRIERSON—Does that mean that you are prejudging who is a risk and who is not.

Mr Slater—Yes.

Ms GRIERSON—Is that based on information?

Mr Slater—It is based on adverse drug reaction reports, intelligence and other objective evidence that we have which would lead us to frame an appropriate random program.

Ms GRIERSON—Audit Office, did you have a view, as a result of this audit, on the frequency of that type of testing? Was it frequent enough? Would you recommend higher degrees of post-market testing of products?

Mr Greenslade—The audit report found that only a very small proportion—I think it was about one per cent—of non-prescription medicinal products are tested annually. I think the recommendation we made was to make sure that that testing was well aligned with any issues that might arise with the manufacturer.

Ms GRIERSON—So you could not discern the reason behind that testing?

Mr Greenslade—I think that is the point, yes. If there are particular problems with a manufacturer they can be picked up with more post-market testing. That goes back to the broader issue of managing risk across the totality of the regulation.

Ms GRIERSON—Did you see any evidence of strategic testing rather than responsive testing?

Ms Nicoll—Certainly in the routine testing. It is split into two areas: the over the counter section and the complementary medicines section. There were good plans. We felt quite comfortable with this whole section. There was the problem on the manufacturing side if the overseas audits had not been conducted that we felt that they could have picked up more of the testing for those manufacturers of the products they produce on that side, and that was our—

Ms GRIERSON—So if there had not been an audit done for some time it might be wise to pick up your level of testing—

Ms Nicoll—That is right.

Ms GRIERSON—just to make sure.

Senator MOORE—Mr Slater, you mentioned earlier that you have put on a lot more auditors, and that came out in the audit report too—that there were small numbers and you had been increasing them. Where do you get them from?

Mr Slater—It has been an age-old struggle for us, because the sorts of individuals that we are seeking are not in great supply. They are usually very highly qualified in an area of science and we also like them to have adequate experience in manufacturing activity, which is a fairly rare confluence of skills. We have been able to recruit. We have been through a targeted head-hunt campaign in the last 18 months and we have been able to attract some very able auditing staff. The problem is not confined to Australia—it is worldwide.

Senator MOORE—In terms of the process, I note that the audit report pointed out that there seems to have been a bit of a change in how long audit actions actually take. I know that we are looking at something that is from 2003 as opposed to 2005, but one of the things that attracted my attention was that from 1999 to 2002 the vast majority of audits took one day or less. That seems to be changing now to a longer process. I know you cannot simplify that, but are you aware of why that is occurring?

Mr Slater—Certainly in 2003 we did some very thorough assessment of particular manufacturers to ensure that any issues we detected in Pan were not endemic. We were duty bound as a regulator to be able to provide assurance to government that this was a one-off, that it was a manufacturer that was not complying and was thumbing its nose at the system and that consumers could rely on the quality of the products that were on the market. Like the rest of the world, if we have an audit frequency or severity—if I could call it that—or level of investigation that provides a technical barrier to trade for Australian manufacturers that would put Australia at a disadvantage, so we tend to line up very much with what is called international best practice in this area—we follow the code and we exchange information with our fellow comparable regulators to ensure that we regulate and audit to the same levels.

Senator MOORE—Do you have any international exchanges so that you swap over and work in each other's areas?

Mr Slater—Yes, we go and join the inspection convention auditing of regulators to ensure that they are complying with the standards that auditing practice demands. As I said, Australia has recently been audited by external auditors in the same way and we got one of the highest ratings that were available. In fact, we are seen to be a world leader—we were the only country that the US FDA recognised and was prepared to accept audit reports from. We have a very high international reputation. But we also inspect other regulatory agencies' audit programs and they inspect ours.

Senator MOORE—You share the knowledge. It is quite a significant increase in the numbers of people working in the area. What is that doing to your budget?

Mr Slater—We are a 100 per cent cost recovery organisation.

Senator MOORE—I have got some good graphs here about the costs and things, but that is up to 2003, so I take it they have risen since then.

Mr Slater—Yes. It goes back also to the 'nought to six months' issue. You would not want to have a situation where you staff to peak workloads. At the end of the day, you staff generally for average workloads. We have staffed for what we see is an appropriate level to make certain that we do not have any audits that are more than six months overdue.

Senator MOORE—You said at the beginning of your statement that you do not have any that are overdue now. That is a significant change from when the audit report was done.

Mr Slater—Yes.

Senator MOORE—Has that been the result of the extra people on board? Is that one of the things that have helped you out?

Mr Slater—It is certainly one of the major factors.

Senator MOORE—The other thing you mentioned earlier was that you have your core group but that you can call in experts.

Mr Slater—Yes.

Senator MOORE—Are these experts in fact consultants that you bring in from time to time or are they on staff?

Mr Slater—They are on staff. They are generally from the laboratories area or from the premarket assessment areas for products.

Ms GRIERSON—After listening to you talk about having to increase your staff and how difficult that might be, I wonder: do you require staff who have specialised training—say, scientific training—but who also need risk management and quality assurance training? Is it a marrying of both those things or are you able to have the risk management and quality assurance experts complemented by scientific experts?

Mr Slater—It would be lovely to have the total combination of all those skills, but we have very intensive auditor training programs. Auditors have to be accredited. Before they are able to undertake any audit, they have to pass through those training programs and get a satisfactory result. Generally speaking our auditors are highly trained scientists, often with a PhD in a particular area. As I said, we want them to have manufacturing expertise so that they bring with them a knowledge of manufacturing activities. Any risk management skills that they can bring with them we applaud. That is very much part of the focus of the training.

Ms GRIERSON—How much of the budget would be spent on training annually?

Mr Slater—We will take that on notice.

Ms GRIERSON—One of the serious deficiencies mentioned in the audit report was record keeping. Everyone in the 21st century knows how difficult it is to process information and to keep good data. But we also know how essential it is. What has TGA done to improve its record keeping and management of information systems?

Mr Slater—As the secretary said, there is a very strong policy within the department to ensure good practice in terms of administration.

Ms Halton—Even if I am failing on folioing.

Mr Slater—Record keeping has certainly been a significant feature of that. The TGA has documents on the staff intranet about the importance of following procedures on record keeping. Part of the induction process for any new starter is an emphasis on record keeping and document management.

Ms GRIERSON—When someone comes out to my factory to audit something, do they have a hand-held system or do they just write it all down on paper? What happens?

Mr Slater—They would have with them whatever they need, as required by their training, to document that audit result. They produce a detailed audit report on the audit.

Ms GRIERSON—But it is mostly a paper system?

Mr Slater—It is basically a paper system, but a number of them carry portable computers.

Senator MOORE—Is there much turnover of staff?

Mr Slater—Generally speaking the TGA does not have a high turnover of staff. I put that down to the fact that we are a unique science based organisation. People tend to love working for the institution. It has a very outstanding international reputation—probably better than it does domestically.

CHAIR—It says a lot for overseas institutions!

Mr Slater—It attracts individuals who wish to work in the public sector. They tend to stay and they get a great deal of satisfaction out of their work with the regulator. There are pockets where we are competing for very scarce resources. We have particular difficulties in relation to medical staff from time to time. We use a lot of external expert committees to supplement the TGA's thinking and also to second-guess it. So for every prescription medicine application or complementary medicine new substance application, for example, we take it to an external committee to look at the four kilograms of paper that we may well take before that committee to ensure that we have reached the right balance between risk and benefit to the patient. Those expert committees are spread right across the TGA. We attract the very best clinicians, professors in their particular field of endeavour and researchers to sit on our committees. It seems to be very prestigious to sit on a TGA expert committee.

Senator WATSON—Fifty-nine per cent of manufacturers by site are actually overseas sites, which are certified by overseas regulators. Do you undertake any tests for countries to ensure that their standards are at least as high or higher than yours? How often do you undertake this sort of evaluation?

Mr Slater—The only countries that we have an arrangement with where we will accept their decisions are what we term comparable countries. They are limited to European countries, Japan, the US, Canada and Singapore—and New Zealand, of course.

Senator WATSON—They comprise 59 per cent—is that right?

Mr Slater—Fifty-nine per cent, with a majority of manufacturers being based in North America and Europe.

Senator WATSON—What steps do you take to make sure that their standards are as high or higher than yours?

Mr Slater—One of the things the ANAO pointed out that we could do better was to have a much more rigorous assessment of how those mutual recognition arrangements are going. Do not forget a number of these are treaty documents, so to an extent, if you like, Australia has entered into these treaties where we are bound to exchange the information and to participate. The ANAO pointed out that we should have a formal review process between the countries to make certain that the arrangements are rigorously in place and that they are giving the sorts of outcomes that we want.

Senator WATSON—And you are proceeding with that?

Mr Slater—We have accepted that recommendation.

Senator WATSON—And you are proceeding with it?

Mr Slater—Yes, and proceeding with it. We have developed a guidance. It happens very much already with the European countries, so the countries that are involved here, Japan and the USA, are the only two that are not already rigorously evaluated by inspections of each other's performance. We are developing agreements with Japan and the USA in line with what we have for European manufacturers.

CHAIR—One last question for the Audit Office: when is the next audit of the TGA due?

Mr Meert—It really depends. Logically, we would wait to see what the consultancy comes up with and have a talk to Health to see about what a suitable time would be. I do not think it would be in the next 12 months by the sound of it. We work with the agency.

Ms Halton—I will sweep the dust underneath the carpet.

CHAIR—They are not exactly guests when they turn up. It is very refreshing to hear about the proactive approach that you have described to us you which you are taking to address all the concerns. In that same context, we await the next audit report to see the benchmark measures against the recommendations that have been placed. Thank you very much for coming along today. We appreciate it.

Ms Halton—I should make the observation that a couple of times people asked whether they could get updates as we go along. If at some point—say, in six months—the committee would like a bit of an overview of how we are proceeding, I would be delighted to provide that to the committee.

CHAIR—Particularly after you have engaged your consultant and set up processes, I think that would be good for the committee.

Ms Halton—We are very happy to do that if it helps the committee.

CHAIR—Thank you very much.

Resolved (on motion by **Senator Hogg**):

That this committee authorises publication, including publication on the parliamentary database, of the transcript of the evidence given before it at public hearing this day.

On behalf of the committee, I would like to thank all the witnesses who have given evidence at the public hearing. I declare the meeting closed. Thank you very much for attending.

Committee adjourned at 3.15 p.m.