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Performance Audit

Management of the Pharmaceuticals Partnerships Program

Department of Industry, Tourism and Resources

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
20 June 2007

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Department of Industry, Tourism and Resources in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit and the accompanying brochure to the Parliament. The report is titled *Management of the Pharmaceuticals Partnerships Program.*

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

Yours sincerely

Ian McPhee
Auditor-General

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

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office. The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Abbreviations

ABL	Agreed Base Level
ANAO	Australian National Audit Office
BPA	Business Partnership Agreement
the Committee	Industry Research & Development Board's Pharmaceuticals Committee
the department	Department of Industry, Tourism and Resources
IR&D Board	Industry Research & Development Board
KRA	Key Risk Area
the Minister	Minister for Industry, Tourism and Resources
the Program	Pharmaceuticals Partnerships Program
R&D	research and development

Glossary

additional R&D	R&D that would not occur in the absence of the Program.
Agreed Base Level (ABL)	Average of previous three years of applicant's expenditure on R&D.
funding agreement (agreement)	Contract for grant funding signed by the recipient and the Commonwealth.
AusIndustry	The division of the department responsible for the delivery of the Program.
Business Partnership Agreement (BPA)	Document which outlines the roles and responsibilities of Innovation Division and AusIndustry for the Pharmaceuticals Partnerships Program.
Industry Research & Development Board (IR&D Board)	The Industry Research & Development (IR&D) Board is responsible for assessing and ranking eligible applications. The IR&D Board has delegated this responsibility to its Pharmaceuticals Committee.
Innovation Division	The division of the department responsible for providing policy advice on, and evaluating, the Program.
Pharmaceuticals Committee (the Committee)	Committee of pharmaceutical industry experts which is delegated by the Industry Research & Development Board to provide technical advice to the Program Delegate.
portfolio	One or more projects identified in the recipient's funding agreement for which grant funding can be claimed.

Program Delegate	Position to which the Minister for Industry, Tourism and Resources has delegated decision-making responsibility for the Program.
research and development (R&D)	Activities undertaken including basic pharmaceuticals research and clinical trials needed for drug registration.

Summary and Recommendations

Summary

Background and context

1. In 2006, Australia's pharmaceuticals industry employed over 34 000 people and had an annual turnover of approximately $17 billion, including almost $3.4 billion in export earnings.[1]

2. The Pharmaceuticals Partnerships Program (the Program) is a $150 million Australian Government program designed to fund companies that forecast a capacity for financing and performing 'additional' high-quality pharmaceuticals research and development (R&D) in Australia. R&D activity undertaken in 2004–05 was estimated to be $643 million.[2]

3. The Program, which is delivered by the Department of Industry, Tourism and Resources (the department)[3], commenced on 1 July 2004 and is funded until 30 June 2009. Companies were able to apply for funding in one of the Program's three rounds held in 2003, 2004 and 2006. Program funding is provided for a 'portfolio' of projects rather than an individual project. Recipients may, with departmental approval, substitute or add suitable projects to their portfolio. This is to accommodate the likelihood that only one in five compounds that enters clinical testing reaches the market.[4] Successful applicants have between two and 69 projects in their portfolios.

4. The Minister for Industry, Tourism and Resources (the Minister) has delegated responsibility for the Program to the General Manager of AusIndustry's Innovation and Collaboration Programs Branch. The Pharmaceuticals Committee (the Committee) of the Industry Research and Development (IR&D) Board provides expert advice to AusIndustry and the Program Delegate.

5. To determine the level of funding to be provided to each recipient, a financial baseline (referred to as the agreed base level or ABL) is set. The ABL

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1 DITR analysis of export figures from *International Merchandise Trade export data from the Australian Bureau of Statistics*, provided 2 February 2007.

2 Gross Expenditure on R&D, by selected socio-economic objective for 2004–05 was advised by Innovation Division based on data provided by the Australian Bureau of Statistics.

3 Within the department, Innovation Division and AusIndustry share responsibility for delivering the Program.

4 Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2007*, Washington, DC: PhRMA, March 2007. Innovation Division advised that although this figure is for the American industry, it is considered to be representative of Australian statistics.

is the average of the company's previous three years of audited R&D expenditure. All expenditure above this ABL is considered to fund additional R&D activity. Recipients are able to claim a refund of 30 cents for each dollar spent above the ABL.

6. An evaluation of the first year of the Program (2004–05) found that the incentive provided by a 30 cents in the dollar payment was too small to significantly change companies' investments in R&D. The refund has been increased to 50 cents for each dollar spent on eligible R&D activity in Round Three (2007–09). This increase is intended to provide a greater incentive for companies that had previously not applied for Program funding.

7. Grants offered to applicants in Rounds One and Two were between $1.8 million and $10 million, which is the maximum available to any recipient. The eleven successful applicants from Round One were offered $87 million and the seven successful applicants from Round Two were offered $47 million.

8. During the first two years of the Program, $54.1 million of additional R&D activity was reported and recipients received $16.2 million in payments.

This audit

9. The objective of this audit was to assess the Department of Industry, Tourism and Resources' management of the Pharmaceuticals Partnerships Program. The audit focused on how the department:

- promoted the Program and assessed applications for funding;
- managed the funding agreements; and
- managed the Program's governance arrangements.

Overall conclusion

10. The Program is a relatively small but complex program, providing funding to recipients for a portfolio of R&D projects. Pharmaceuticals R&D is, by nature, high risk and portfolios are likely to change over the period of the funding agreement. Recipients may regularly vary their agreements, and carry under and overperformance against financial forecasts into future years.

11. Overall, the Program is being managed effectively by the department. The communication strategy developed by AusIndustry was effective in promoting the Program across the pharmaceuticals industry. AusIndustry has also developed and implemented effective processes for assessing and ranking

applicants against the Program's eligibility and merit criteria. Key decisions made by the Program Delegate were also appropriately documented.

12. A Compliance Management Strategy has been developed and implemented to monitor recipients' compliance with their funding agreements. However, recipients' risk ratings were not always consistent with the risk criteria outlined in the strategy and not all criteria used to assess recipients' compliance risks were included in the strategy. Compliance targets should be based on recipients' risk ratings and revised as necessary when these ratings change. This will enable monitoring activities to address current and emerging risks.

13. The Program is supported by a sound governance framework. The department has assessed the Program's risk rating as 'high' because of its considerable underspend against recipients' financial forecasts. Payments to recipients in the first two years of the Program were almost 60 per cent and 40 per cent less than their revised financial payment forecasts.[5] In AusIndustry's view, this is because of the high risk nature of pharmaceuticals R&D activity and was the reason for incorporating into the Program a number of features designed to manage this risk. However, allowing recipients to carry under and overperformance into future years also means that the risks associated with the Program's underspend may increase in the later years of the Program.

14. Also, if the Program's risks are to be effectively managed, recipients' performance needs to be recognised as a major source of risk and included in the risk analysis underlying the Program's Risk Management Plan.

15. Currently, there is no ongoing assessment of whether the Program is meeting its overall objective, or two of its sub-objectives. Performance data is collected for all Program sub-objectives, but only expenditure data is reported.

16. The proposed Program evaluation scheduled for the first half of 2007–08 will measure some important aspects of the Program. However, it will be difficult to deliver a complete assessment on whether the Program's overall objective is being met because the industry-wide data being collected does not address the quality of the R&D activity being undertaken.

[5] In 2004–05, the original forecast of $14.7 million was revised to $11 million, with actual payments of $4.7 million being made. In 2005–06, the original forecast of $19.7 million was revised to $18.8 million with actual payments of $11.5 million being made.

17. The ANAO has made two recommendations to improve the management of the Program. The report also highlights a range of lessons (based on departmental and ANAO experience) to bear in mind for future R&D assistance programs.

Key findings

Program awareness and assessing applications for funding (Chapter 2)

Awareness and promotion of the Program

18. Pharmaceuticals companies had three opportunities to apply for funding under the Program in application rounds held in 2003, 2004 and 2006. For each round AusIndustry developed and implemented an effective communication strategy. AusIndustry assessed the effectiveness of its promotional activities in May 2005. Survey responses to its Customer Satisfaction Survey indicated that 86 per cent of applicants knew that information relating to the Program was available from the Hotline and website. The Program evaluation undertaken in late 2005 also found that eligible companies that did not apply for funding were aware of the Program and information sources.

Assessment process

19. Applications were assessed against the Program's eligibility criteria by AusIndustry and against the merit criteria by the Industry Research and Development Board's Pharmaceuticals Committee (the Committee). The ANAO reviewed the 26 applications received in Round One and the 11 applications received in Round Two. There was evidence to support the eligibility of each applicant; and assessment checklists were completed for each application and countersigned by a second reviewer. Delegations were also appropriately exercised in each round.

20. For the merit assessment process, applicants provided financial data and information for each R&D project in their portfolios. The ANAO found that:

- the Committee assessed and ranked applicants against the Program's merit criteria;

- Committee members' potential conflicts of interest were managed well and in accordance with pre-established procedures;
- the Probity Advisor, appointed to oversee the assessment, found that the process was transparent and met probity requirements; and
- after each round the assessment criteria were reviewed and amended for practicality and better alignment with the Program's objective.

Management of funding agreements (Chapter 3)

Negotiating the funding agreements

21. To receive funding under the Program, each successful applicant must sign a funding agreement (agreement) with the Commonwealth. AusIndustry commenced negotiating the agreements with successful applicants from Round One in April 2004 and from Round Two in April 2005. Funding was offered from 1 July of the same year. Delays in finalising the agreements in both Rounds meant that there were no agreements in place by 1 July in either year. Delays were generally caused because an applicant's portfolio of R&D projects had changed since the application had been submitted. Despite the delays, recipients' access to funding was not affected as payments are made in arrears and all agreements were signed before the first payment was available in October of that year.

Recipient reporting and calculation of payments

22. The amount of grant funding offered to each recipient is based on the expenditure forecasts provided in their applications. Payments are made quarterly, in arrears and calculated from the financial information submitted each year by recipients in their quarterly and annual reports.

23. A payment to the recipient is due if the quarterly report includes actual R&D expenditure for that quarter that is greater than one-quarter of the ABL.[6] The payment based on the annual report is a 'balancing' payment. A payment will be due if the recipient's actual audited expenditure for the entire year exceeds the full ABL and the payment due exceeds the combined total of payments made in any of the previous three quarters. In addition, the payment due to a recipient will be affected by:

[6] The quarterly payment is capped at 25 per cent of the maximum annual grant payment for the first quarter and this capped rate increases to 50 per cent and 75 per cent for subsequent quarters.

- any overpayments that have already been made;
- the recipient receiving other government grant payments; and/or
- underperformance or overperformance in previous years.

24. An overpayment can occur when the actual annual payment due is less than the combined total of quarterly payments already made. In 2004–05 and 2005–06, six companies were overpaid approximately $1.5 million. The amounts varied between $8000 and $700 000. Under the agreement, these amounts must be repaid to AusIndustry and should be accounted for by the department as either a prepayment[7] or a receivable.[8] AusIndustry recorded these overpayments as an expense. AusIndustry advised that, in future, all overpayments will be correctly recorded.

25. Funding offered to each recipient is based on their forecast R&D expenditure. In practice, recipients' actual expenditure can differ considerably from their forecast expenditure. The agreement, in certain circumstances, allows:

- unused funding resulting from a recipient's underperformance (where forecast expenditure exceeds actual expenditure) to be carried forward into the following year; and
- additional funding earned from a recipient's overperformance (where actual expenditure exceeds forecast expenditure) to be paid out or used to offset underperformance in the previous year or future years.

26. The ANAO observed that, across the two-year period, there were 20 instances where recipients underperformed against their expenditure forecasts. Of these, 12 recipients were unable to carry forward their unused funding as they did not meet the conditions of the agreement.[9] As a consequence, the Program is considerably underspent. To manage this underspend, funding foregone by recipients in 2004–05 and 2005–06 was made available to Round Three applicants.

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7 A prepayment is where the overpayment can be offset by subsequent payments as permitted by the agreement.

8 Where the Program Delegate considers that an overpayment will not be offset within a reasonable period of time, the delegate will declare the amount a debt and AusIndustry will seek repayment within 30 days.

9 Actual expenditure must exceed 75 per cent of annual forecast expenditure and the payment due must be at least 50 per cent of the maximum annual payment.

Managing Compliance

27. Managing a recipient's compliance with their agreement should provide assurance that the grant funding is being used appropriately and that each recipient is meeting the conditions for receiving that funding. AusIndustry has three mechanisms for managing a recipient's compliance: varying the agreement; its Compliance Management Strategy (strategy); and ad hoc reviews.

Variations to funding agreements

28. AusIndustry accepts that there will be some variation at the portfolio level due to projects failing, new projects starting and expenditure forecasts being revised. To address the changing circumstances of recipients, the agreement allows for the Program Delegate to approve variations to the portfolio. The ANAO considers that varying the agreement is a practical way of addressing the difficulties recipients have in forecasting their R&D projects and expenditure. As of October 2006, 16 variations had been requested and these have resulted in the addition of 27 projects and the removal of 11 projects. Overall, these variations did not affect the Program's future funding profile.

Compliance Management strategy

29. AusIndustry has implemented a Compliance Management Strategy to monitor recipient compliance with their agreements. This strategy sets out the:

- basis for determining a recipient's risk rating;
- activities to be undertaken at each compliance level; and
- number of activities (targets) that will be undertaken annually for each compliance level.

Determining recipients' compliance risk ratings

30. A recipient's compliance risk rating is assessed against the risk criteria outlined in the strategy. This risk rating is revised as necessary after the quarterly and annual reports have been evaluated. The ANAO reviewed the recipients' compliance risk ratings for 2004–05 and 2005–06, and found the ratings were not always consistent with the risk criteria in the strategy. For example, in six instances, AusIndustry did not apply a 'high' rating although the risk criteria for this rating had been met. As a consequence, recipients may have received a lower level of compliance monitoring. The strategy also needs

to include all criteria used by AusIndustry to assess recipients' compliance risks.

Levels of compliance activity and compliance targets

31. The strategy escalates compliance activity through four levels. Monitoring activities are primarily company visits and the evaluation of recipients' quarterly and annual reports. The number of activities (or targets) to be undertaken annually for each compliance level are also outlined.

32. The Program's operating procedures and the strategy indicate that at least one visit will be made to each recipient from Rounds One and Two in the first two years of the Program. As of March 2007, only three of the 11 recipients from Round One have received a compliance visit whereas all six Round Two recipients have been visited.

33. Recipients have submitted all necessary reports. Of the 101 reports due, 52 were received on or before the due date. All other reports were received within 30 days of the due date. The annual report includes an audit statement verifying the actual expenditure and that the expenditure complies with the Program guidelines.

Setting compliance targets

34. The recipient's risk rating determines the extent of monitoring activity to be undertaken. These risk ratings should be the basis for setting annual compliance activity targets. However, this currently does not occur. AusIndustry advised that the compliance targets are based on previous outcomes and Program developments. The strategy is updated annually in April/May (in preparation for the next financial year). The compliance targets set at this time should be based on the recipients' risk ratings and revised if these ratings change. This will ensure that the activities being undertaken are addressing current and emerging risks.

Ad hoc reviews

35. The Program's operating procedures and funding agreements outline that an ad hoc review will be conducted when a recipient's annual report shows:

- actual expenditure is less than their ABL;
- the annual payment is less than 75 per cent of the forecast payment; or
- milestones have not been met to a sufficient degree.

36. In 2005–06, AusIndustry conducted two ad hoc reviews. The ANAO's analysis of the financial information reported by recipients in their annual reports indicated that an additional four recipients in 2004–05 and an additional five recipients in 2005–06 had met the requirements for a review. AusIndustry advised that it did not conduct a review if the recipient requested a variation to their agreement or where they were able to satisfy AusIndustry that an ad hoc review was not necessary. Two recipients will also be required to substantiate their continued participation in the Program as part of a compliance visit in 2006–07.

37. Ad hoc reviews were part of the Program's Compliance Management Strategy for first year of the Program (2004–05) but were removed in later years. As an ad hoc review is a compliance activity, the ANAO considers that, in any future programs, the review should form part of the strategy. Acceptable alternatives to a review should, ideally, be identified in the strategy and Program's operating procedures. Also, where a review is triggered but not conducted, there would be benefit in AusIndustry re-assessing the need for a review following receipt of the recipient's next quarterly report. This would alert AusIndustry to any ongoing compliance issues.

Governance arrangements (Chapter 4)

Planning

38. AusIndustry's planning documents are comprehensive and outline the responsibility and reporting requirements at each level. The plans are updated at least annually, and more frequently, if changes impact on the Program. They also provide a structure for activity to be reported monthly and quarterly to AusIndustry's Executive Committee and monthly at the department's Portfolio Managers' Meeting.

Risk Management

39. AusIndustry's risk management framework supports the delivery of the Division's primary role, which is *delivering the policy objectives of each of our programs.* This framework consists of a series of related plans. These include: the AusIndustry Risk Management Plan; AusIndustry Risk Priorities for Programs; and Program Risk Management Plan.

Program risks

40. The Program Risk Priority, which compares risks across all AusIndustry's programs, has been rated as 'moderate', for each year of the

Program. At the program level, risks are assessed against the five Key Risk Areas (KRAs) in the Program Risk Management Plan.[10] The Program has been rated consistently as a 'high' risk because of underperformance against the financial management KRA. The current strategies to treat this financial risk include: carrying forward recipients' underperformance; re-phasing expenditure into future years; re-allocating funding to recipients in the final round; and/or paying out a recipient's overperformance.

41. The ANAO's analysis of AusIndustry data has shown that the total payments made were almost 60 per cent and 40 per cent less than agreed forecasts for years one and two respectively. The current treatment strategies are compounding this effect as, generally, they are moving underperformance (that is, expenditure is less than forecasted) and budget allocations into the remaining years.

Risks associated with recipients

42. The current Program Risk Management Plan identifies a number of risk categories but does not identify recipients' performance as a major source of risk, although some of the mitigation strategies are directed towards this. AusIndustry advised that the recipients' compliance risk ratings are considered collectively when assessing the Program's risks. However, it was unable to provide documentation to support how these ratings are considered when identifying Program risks. If Program risks are to be effectively managed, the inclusion and analysis of recipients' compliance risks need to be documented and incorporated in the Program Risk Management Plan.

Performance management

43. An appropriate performance management framework should enable the department to monitor and measure the Program's progress towards achieving its objective and sub-objectives. The Program's overall objective is *to increase the level of high quality pharmaceuticals R&D undertaken in Australia.*[11] The Program also has the following sub-objectives:

- promoting additional, high quality R&D across the pharmaceuticals industry above what would have been done in the absence of the Program;

[10] The five Key Risk Areas are financial management, outcomes and objectives, service delivery, program governance, and compliance and fraud.

[11] Agreed in the *Business Partnership Agreement between Innovation Division and AusIndustry,* 4 October 2004.

- encouraging the development of medicines for global markets; and
- encouraging partnerships and linkages between multinational firms and local players.

Industry baseline data

44. The department collects biennial expenditure data for pharmaceuticals R&D activity in Australia from the Australian Bureau of Statistics.[12] It has recently been advised that this information is available annually and will now use 2003–04 data as the baseline to measure the increase in industry-wide R&D activity generated by the Program.[13] However, this data does not address the quality of R&D activity being undertaken. Consequently, there is no baseline data available to assess whether an increase in the level of pharmaceuticals R&D being undertaken is of the same quality required by the Program.

Recipients' performance data

45. Recipients are required to provide, in their annual reports, performance information relating to the Program's three sub-objectives. This includes: the commercialisation of research; R&D collaborations and contract research; and actual expenditure. AusIndustry collects this data on behalf of Innovation Division. AusIndustry reports expenditure data but commercialisation and collaborations data are not reported by either AusIndustry or Innovation Division. Innovation Division advised that this information may be used for policy development, when providing advice to the Minister and will be used for the proposed evaluation in the first half of 2007–08.

R&D expenditure data

46. The reported increase in R&D activity was $15.8 million (9.7 per cent) in 2004–05 and $38.3 million (16 per cent) in 2005–06. The total payments made in 2004–05 were $4.7 million and, in 2005–06, $11.5 million. This data indicates that, although there has been an increase in R&D activity, the Program is considerably underspent against its allocation of $150 million.[14] For the first year of the Program the increase in R&D expenditure by recipients was broadly in line with the 12.6 per cent ($71.7 million) growth in R&D expenditure industry-wide. Industry data is not yet available for 2005–06.

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[12] R&D statistics were collected annually for business and biennially for higher education, general government and private non-profit organisations.

[13] Prior to sourcing this annual data the department had intended using the average of 2002–03 and 2004–05 data.

[14] The total payments made were almost 60 per cent and 40 per cent less than agreed forecasts for years one and two respectively.

Performance reporting

External reporting

47. Reporting of all AusIndustry Output One programs, including this Program, are aggregated in the department's annual reports. Therefore, very limited Program information is available publicly. The IR&D Board and the department only briefly mention Program activities in their annual reports.

Internal reporting

48. Monthly and quarterly reports provided to the AusIndustry Executive Committee for both years of the Program were reviewed. The monthly reports primarily focus on program delivery with indicators covering: the number of applications in a round; the number of successful applicants; and the time taken to negotiate agreements. While these indicators are useful for assessing the quality of AusIndustry's service delivery and the quantum of activity undertaken, they do not measure the progress being made towards achieving the Program's objective or sub-objectives.

49. Quarterly reports list outcome performance indicators such as: additional R&D expenditure; the number of new collaborations, and the number of pharmaceuticals that reach product registration. AusIndustry collects this information on behalf of Innovation Division. However, as previously noted, with the exception of expenditure data, this information is not reported within the department but will be used when evaluating the Program.

Agency response

50. The Department of Industry, Tourism and Resources is pleased with the ANAO's conclusion that 'the Program is being managed effectively by the department' (paragraph 11) and that 'the Program is supported by a sound governance framework' (paragraph 13). The Department accepts the recommendations for the management of the Program. The adoption of minor improvements in the compliance management of recipients and their individual risk assessment will strengthen the delivery of the Program.

51. The Department's full response can be found at Appendix 1.

Recommendations

Set out below are the ANAO's recommendations for improving the Department of Industry, Tourism and Resources' administration of the Pharmaceuticals Partnerships Program. Report references and the department's abbreviated responses are provided.

Recommendation No. 1
Paragraph 3.39

To enable compliance monitoring activities to address the current risks posed by recipients to the Program, the ANAO recommends that AusIndustry:

(a) include in its Compliance Management Strategy all criteria to be used in assessing compliance risks; and

(b) base compliance targets on recipients' risk ratings and revise targets as necessary when risk ratings change.

DITR response: Agreed.

Recommendation No. 2
Paragraph 4.12

To provide a comprehensive assessment of the risks facing the Pharmaceuticals Partnerships Program, the ANAO recommends that AusIndustry, in its Program Risk Management Plan:

(a) includes recipients' performance as a major source of risk; and

(b) reviews current strategies for mitigating identified risks.

DITR response: Agreed.

Audit Findings and Conclusions

1. Background and Context

This chapter describes the Department of Industry, Tourism and Resources' role in developing and administering the Pharmaceuticals Partnerships Program. The audit objective and scope are also outlined.

Background

1.1 In 2006, Australia's pharmaceuticals industry employed over 34 000 people and had an annual turnover of approximately $17 billion, including almost $3.4 billion in export earnings.[15]

1.2 Research and development (R&D) activity undertaken in 2004–05 was estimated to be $643 million.[16] The Department of Industry, Tourism and Resources (the department) administers a range of programs that support R&D activity. Pharmaceuticals companies may be eligible for assistance from more than one of these programs, which include:

- the Pharmaceuticals Partnerships Program (the Program)—a competitive entry program supporting 'additional' R&D activities. Pharmaceuticals companies can claim a refund of up to $10 million.
- Commercial Ready—a competitive entry program, which provides grants of up to $5 million per project to small to medium businesses undertaking R&D, proof-of-concept and early stage commercialisation activities; and
- R&D Tax Concession—a broad-based tax concession available to companies that conduct their R&D in Australia and also hold the relevant intellectual property in Australia.

The Pharmaceuticals Partnerships Program

1.3 The Program, which commenced on 1 July 2004, was allocated funding of $150 million over five years.[17] Unlike Commercial Ready and the R&D Tax Concession, eligibility for a grant under the Program is not restricted by the size of the company nor is it tied to the recipient's ownership of the intellectual property on which the R&D is based.

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[15] Export figures were provided by Innovation Division from International Merchandise Trade export data supplied by the Australian Bureau of Statistics, 2 February 2007.

[16] Gross Expenditure on R&D, by selected socio-economic objective for 2004–05 was advised by Innovation Division based on data provided by the Australian Bureau of Statistics.

[17] This figure includes $10 million that was later transferred to the Mammalian Cell Research Facility.

1.4 The Program is the third in a series of support programs specifically targeting the pharmaceutical industry and the first program to be administered by AusIndustry. Predecessor programs were the *Pharmaceuticals Industry Investment Program* (1999–2004) and *Factor f* (1988–1999). The Program has been developed in association with the pharmaceuticals industry through an Action Agenda.[18] The Productivity Commission's 2003 review of the Pharmaceuticals Industry Investment Program was also considered.[19] This review concluded that a new program should focus on generating R&D activity above a baseline and support a portfolio of R&D projects rather than an individual project. The review also found that this approach was more likely to generate a much higher level of additional activity than other R&D incentives in Australia and overseas.

1.5 The Program's overall objective is *to increase the level of high quality pharmaceuticals R&D undertaken in Australia*. The Program also has the following sub-objectives:

- promoting additional, high quality R&D across the pharmaceuticals industry above what would have been done in the absence of the Program;
- encouraging the development of medicines for global markets; and
- encouraging partnerships and collaborations between multinational firms and local players.

Applying for the Program

1.6 Companies applied for funding in one of the Program's three funding rounds in 2003, 2004 and 2006. Applications were assessed against the eligibility criteria in the Program guidelines and merit criteria set out in Ministerial Directions.[20] The Program allows funding to be claimed for a 'portfolio' of projects (rather than an individual project). The Program Delegate[21] allows recipients to substitute or add suitable projects to their

[18] Action Agendas aim to foster industry leadership and help industries develop strategies for growth, agree on priorities and make commitments to change. Sourced on 22 March 2007 from <www.industry.gov.au>.

[19] Productivity Commission, *Evaluation of the Pharmaceuticals Industry Investment Program,* January 2003.

[20] *Pharmaceuticals Partnerships Program Directions No. 1 of 2003, Pharmaceuticals Partnerships Program Directions No. 1 of 2004* and *Pharmaceuticals Partnerships Program Directions No. 1 of 2006,* issued by the Minister for Industry, Tourism and Resources.

[21] The Minister for Industry, Tourism and Resources has delegated responsibility for the Program to the General Manager of AusIndustry's Innovation and Collaboration Programs.

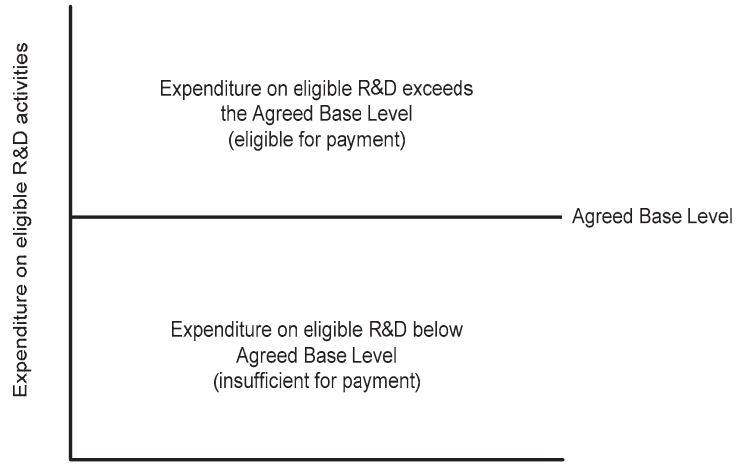
portfolio. This is to accommodate the likelihood that only one in five compounds that enters clinical testing reaches the market.[22] Successful applicants have between two and 69 projects in their portfolios.

Grant funding offered to recipients

1.7 For each recipient, a financial baseline is set using an average of the company's previous three years of audited R&D expenditure. The baseline, which is illustrated in Figure 1.1, is referred to as the Agreed Base Level (ABL). All expenditure above the ABL is considered to fund additional R&D and, as such, the recipients in Rounds One and Two can claim a refund of 30 cents for each dollar spent.

Figure 1.1

Agreed Base Level



Source: ANAO analysis of AusIndustry data

1.8 Payments are taxable, paid quarterly in arrears and are based on a recipient's reported actual expenditure. An evaluation of the first year of the Program (2004–05) found that the incentive provided by a 30 cent in the dollar payment was too small to significantly change companies' investments in R&D. The refund has been increased to 50 cents for each dollar spent on eligible R&D in Round Three (2007–09). This increase is intended to provide a greater incentive for companies that had previously not applied for Program funding.

[22] Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2007*, Washington, DC: PhRMA, March 2007. Innovation Division advised that although this figure is for the American industry, it is considered to be representative of Australian statistics.

1.9 The funding offered to a successful applicant is based on the difference between the ABL and the applicant's overall expenditure forecasts. Eleven successful applicants from Round One were offered a total of $87 million in funding and seven successful applicants from Round Two were offered a total of $47 million.[23] During the first two years of the Program, $54.1 million of additional R&D activity was reported and recipients received $16.2 million in payments.

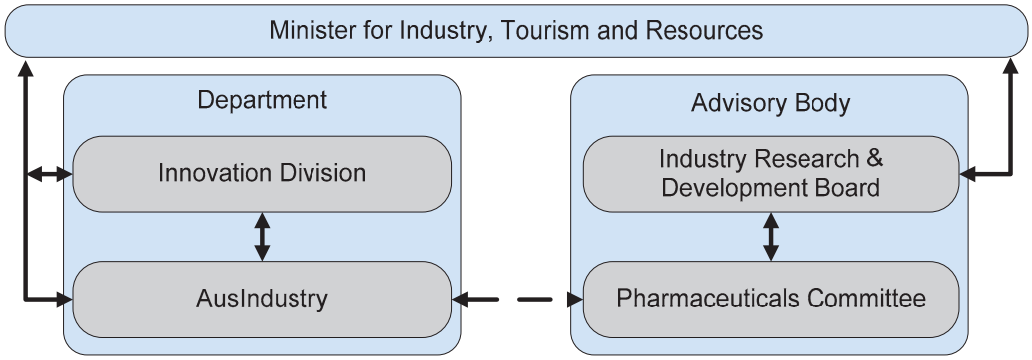
1.10 A funding agreement (agreement) is signed between each successful applicant and the Program Delegate (on behalf of the Commonwealth) and establishes the terms and conditions for receiving the grant funding. Recipients are required to provide quarterly and annual reports. The annual report is to include an audit statement, which verifies the actual expenditure incurred in the payment year and that the expenditure complies with the Program guidelines.[24]

Program delivery

1.11 Within the department, Innovation Division and AusIndustry share accountability for delivering the Program. The Industry Research & Development (IR&D) Board[25], through its Pharmaceuticals Committee (the Committee), provides expert advice to AusIndustry and the Program Delegate. The relationship between the partners is illustrated in Figure 1.2.

Figure 1.2

Entity relationship for Pharmaceuticals Partnerships Program



Source: ANAO analysis of AusIndustry data

[23] Grants offered to applicants ranged from $1.8 million to $10 million (the maximum available).

[24] The audit of actual expenditure must be performed by either a registered company auditor or an authorised audit company, neither of which are an associate, employee, shareholder, director or other officer holder of the participant or a member of the group.

[25] The Industry Research & Development Board is an independent statutory body that was established on 1 July 1986 under the *Industry Research and Development Act 1986*.

The Business Partnership Agreement

1.12 Innovation Division and AusIndustry jointly deliver programs and have formalised this relationship through a Business Partnership Agreement (BPA).[26] The BPA outlines the roles and responsibilities of each partner in relation to the Program.

AusIndustry

1.13 AusIndustry administers the Program and is responsible for:

- assessing the eligibility of applications;
- managing the agreements;
- managing the governance relationship with the IR&D Board through the Pharmaceuticals Committee;
- providing advice and performance information to Innovation Division to assist them to measure the Program's success; and
- maintaining Program data on AusIndustry's centralised Grants and Loans Activity Management database.

Innovation Division

1.14 Innovation Division consults with the pharmaceuticals industry and AusIndustry to aid policy design, policy initiatives and Program evaluation. This role includes the development and review of new policy options and any additional policy development that contributes to the Program better achieving its objectives. The Division will undertake a formal evaluation of the Program in the first half of 2007–08, to determine how effective the Program has been in meeting its objective and sub-objectives.

Pharmaceuticals Committee

1.15 The Minister established the Pharmaceuticals Committee of the IR&D Board (the IR&D Board) in September 2003. At this time, the IR&D Board's roles and responsibilities in the Pharmaceuticals Partnerships Program Directions were delegated to the Committee.[27] The Committee is responsible for assessing the merit of each application and providing advice to the Program Delegate. If the Committee is unable to form a quorum because

[26] The *Business Partnership Agreement between Innovation Division and AusIndustry* was signed on 4 October 2004.

[27] *Pharmaceuticals Partnerships Program Directions No.1 of 2003, Pharmaceuticals Partnerships Program Directions No. 1 of 2004* and *Pharmaceuticals Partnerships Program Directions No. 1 of 2006.*

members have potential conflicts of interest, the IR&D Board is required to complete the merit assessment and ranking of applications.

Previous reviews of the Program

1.16 In 2005, an evaluation of the Program and an internal audit review were conducted. The evaluation, conducted by the Centre for International Economics, found that after one year, the Program was highly regarded by industry. Evidence pointed to a small net positive contribution to the Australian economy of approximately $30 000.[28] The internal audit found that, generally, the governance arrangements for the Program represented good practice, handling of agreements was appropriate and the Program's risks had been appropriately addressed.[29]

Audit objective, scope and methodology

1.17 The objective of this audit was to assess the Department of Industry, Tourism and Resources' management of the Pharmaceuticals Partnerships Program. The audit focused on how the department:

- promoted the Program and assessed applications for funding;
- managed the funding agreements; and
- managed the Program's governance arrangements.

Audit methodology

1.18 The audit methodology included quantitative and qualitative analysis, file and documentation reviews and interviews with agency staff and the previous Chairman of the Pharmaceuticals Committee. Interviews were also conducted with a number of Program participants.

1.19 The ANAO reviewed all applications (37) and agreements (17)[30] for Rounds One and Two of the Program. Fieldwork was completed before Round Three closed in November 2006.

1.20 The audit was conducted in accordance with ANAO auditing standards, at a cost of $372 000.

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[28] The model used to estimate the net positive contribution was based on a range of assumptions from the evaluation survey results and recipients' annual reports.

[29] These reviews and the results are outlined further in paragraphs 4.38–4.39.

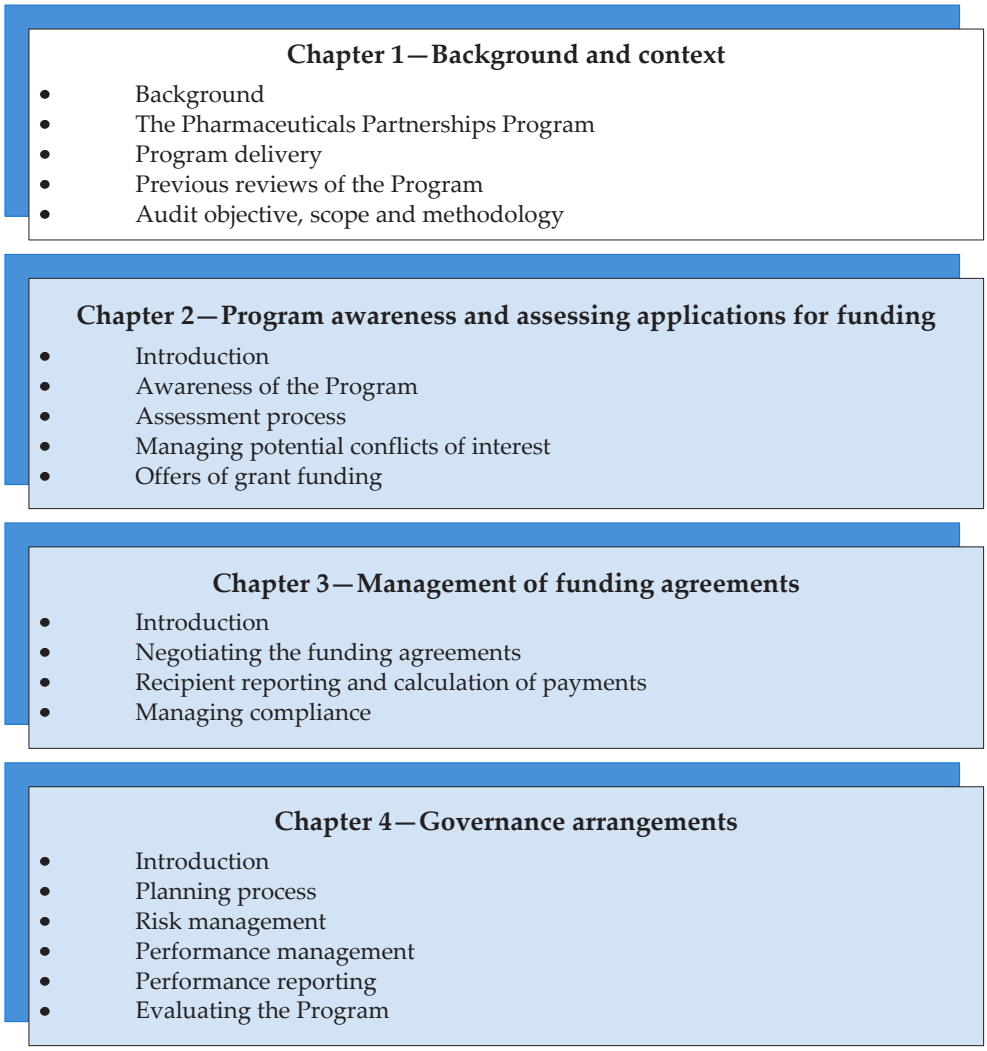
[30] One successful applicant from Round Two withdrew from the Program before the funding agreement was finalised.

Structure of the report

1.21 Figure 1.3 illustrates the framework used by the ANAO to examine the Pharmaceuticals Partnerships Program. This framework forms the basis of this report.

Figure 1.3

Report structure



2. Program Awareness and Assessing Applications for Funding

This chapter reviews how AusIndustry generated awareness of the Program for each application round and how applications were assessed and recipients selected in Rounds One and Two.

Introduction

2.1 AusIndustry is responsible for ensuring that the pharmaceuticals industry is aware of the Program and eligible pharmaceuticals companies have a fair and equal opportunity to apply for funding. It is also responsible for managing the assessment and selection processes.

2.2 The ANAO reviewed:

- AusIndustry's strategy for promoting the Program to the pharmaceuticals industry;
- the eligibility and merit assessments of applications received in Rounds One and Two; and
- the decision-making process for selecting successful applications in Rounds One and Two.

Awareness of the Program

2.3 The pharmaceuticals industry has a well-organised stakeholder group and the department has established a close working relationship through its previous R&D assistance programs and industry action agenda. The department advised that of the 120 pharmaceuticals companies in Australia, approximately 60 of these companies undertake R&D activity and could be considered eligible for the Program.

Promoting the Program

2.4 Pharmaceuticals companies had three opportunities to apply for funding under the Program with application rounds being held in the 2003, 2004 and 2006. For each round, AusIndustry developed and implemented a communication strategy to disseminate information to identified potential applicants. This included advertising the opportunity to apply to the Program in national newspapers and pharmaceutical industry specific magazines and

journals and on *www.grantslink.gov.au*[31], *www.business.gov.au*[32] and the AusIndustry website *www.ausindustry.gov.au.* Further, potential applicants had the opportunity to ask questions about the Program at seminars held in Sydney, Melbourne, Adelaide and Brisbane during both rounds. Invitations were sent directly to potential applicants identified from previous programs and through industry contacts.

2.5 The ANAO reviewed material relating to the promotion of each application round and concluded that the awareness activities conducted by AusIndustry were comprehensive and effective. Potential applicants were provided with consistent and useful information. All advertising directed potential applicants to the AusIndustry Hotline and the AusIndustry website for further information.

2.6 AusIndustry also assessed the effectiveness of its promotional activities in May 2005 through a Customer Satisfaction Survey.[33] Survey responses indicated that 86 per cent of applicants knew that information relating to the Program was available from the Hotline and on the website. The Program evaluation undertaken by the Centre for International Economics[34] in late 2005 also found that eligible companies that did not apply for Program funding were aware of the Program's objective, funding rounds and where further information about the Program could be sourced.

Assessment process

2.7 AusIndustry developed the assessment process for the Program based on its experience in administering other grant programs. The process is intended to deliver a transparent and fair selection decision. The eligibility and merit criteria for assessing applications are outlined in the *Guidelines for the Pharmaceuticals Partnerships Program.*[35]

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31 A website linking individuals, businesses and communities to a multitude of community grant programs.

32 A website linking business to Commonwealth, State/Territory and Local government grants programs.

33 ORIMA Research, *AusIndustry Customer Satisfaction Survey Report: Pharmaceuticals Partnerships Program*, May 2005. The Customer Satisfaction Survey randomly selected and surveyed 23 applicants from the 33 applicants in both rounds.

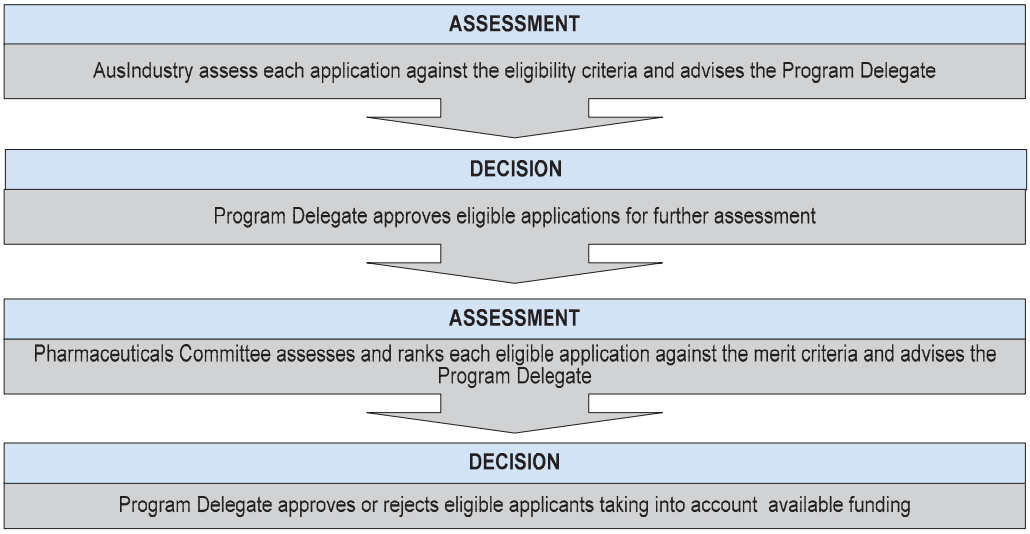
34 Centre for International Economics, *Pharmaceuticals Partnerships Program First Year Evaluation*, 27 February 2006. Successful, unsuccessful and non-applicant companies that were surveyed are at pp. 63–64.

35 The merit criteria are also defined in Ministerial Directions.

2.8 Applications were initially assessed by AusIndustry to determine whether the applicant was eligible to apply to the Program.[36] The Pharmaceuticals Committee then assessed and ranked the merits of each eligible application against the merit criteria.[37] The Program Delegate[38] decided, which applicants were eligible and, subsequently, which were to be offered funding. The assessment and decision-making process is illustrated in Figure 2.1.

Figure 2.1

The application assessment and decision-making process



Source: ANAO analysis of AusIndustry data

Assessing applications against the eligibility criteria

2.9 The same set of eligibility criteria was used in Rounds One and Two and applicants were expected to provide evidence to support each of the four criteria. For each criterion, AusIndustry validated the applicant's claims and documented its assessment on a Pre-assessment Eligibility Checklist. The Program Delegate used this assessment to determine an applicant's eligibility for the Program. The ANAO reviewed the documentation provided to the

[36] Eligibility criteria included: the Company must be incorporated under Australian Corporation Law; involved in the discovery, creation or supply of pharmaceuticals; have a three-year track record of eligible R&D activity in Australia; and intend to conduct more eligible R&D activity in Australia.

[37] The merit criteria are outlined in paragraph 2.11.

[38] The Minister for Industry, Tourism and Resources has delegated responsibility for the Program to the General Manager of AusIndustry's Innovation and Collaboration Programs.

delegate for each of the 26 applications received in Round One and the 11 applications received in Round Two and found that:

- each checklist was completed and countersigned by a second reviewer;
- there was evidence to support the eligibility of the applicant; and
- the delegation had been appropriately exercised in each round.

2.10 Only applications deemed to be eligible by the Program Delegate proceed to merit assessment. To date, no application has failed the eligibility assessment.

Assessing the merit of applications

2.11 The merit of applications is assessed and ranked against the following merit criteria:

- track record and capabilities;
- scope and nature of partnerships and collaborations;
- technical merit of the proposed activities;
- level of benefit to the Australian economy; and
- sustainability of an internationally competitive pharmaceuticals industry in Australia (Round One only).

2.12 The applicant provides financial data and information for each R&D project in their portfolio. This includes expenditure and milestone projections for each year that they are seeking funding. The applicant is required to sign a declaration that the information provided in the application is true and correct.

2.13 Each criterion is weighted equally. To merit rank the applications, the Committee assessed each application and recorded comments and a score out of six against each merit criterion. These comments were aggregated and the scores averaged and recorded on a Rating Assessment Sheet.[39] The ANAO reviewed the Rating Assessment Sheet for each application received in Rounds One and Two and found these documented the strengths and weaknesses of each application in detail. Initially, each application was given a provisional score and ranking based on this assessment.

[39] The numerical score between zero and six correlates to a word score and definition. For example, a numerical score of 'four' represents 'Good: most factors under the selection criteria are met to a reasonable standard. [There] may be some weaknesses in limited areas'.

2.14 In both rounds, the Committee interviewed applicants to clarify information in their application and enable the rankings to be finalised. In Round One, seven applicants were offered an interview and six were interviewed (one company withdrew its application). In Round Two, six applicants were interviewed.

2.15 AusIndustry advised applicants and the Committee that interviews were not an opportunity for applicants to introduce new information. The ANAO reviewed the list of questions sent to each interviewee and the minutes from the interviews and confirmed the questions asked by the Committee members related to information in the applications. In addition, the Probity Advisor (engaged to aid the transparency of the application process) was present for both sets of interviews and did not raise any objections.

2.16 The ANAO reviewed the provisional scores (pre-interview) and the final scores (post-interview) to measure the impact of interviews on applicant success. Applicants who scored an average rating of four or better against each merit criterion were ultimately successful. The ANAO's analysis showed that three applicants moved from a 'successful' score pre-interview to an 'unsuccessful' score post-interview. No recipient moved from an 'unsuccessful' pre-interview score to a 'successful' score post-interview.

Program improvements

2.17 After each round, the Pharmaceuticals Committee, Innovation Division and AusIndustry have reviewed and amended the merit criteria for practicality and better alignment with the Program's objective. For example, at the end of Round One, the Committee noted repetition in applicants' responses for criterions four and five. Subsequently, these criteria were combined to form merit criterion four, for Round Two. The same four merit criteria have been used for Round Three.

2.18 Applicants for Round Three are required to provide evidence of all intended partnerships claimed in their application. AusIndustry advises that these changes were made because applicants selected in Round Three will only have two years to establish the intended partnerships and undertake the associated R&D activity.

Managing potential conflicts of interest

2.19 The seven Committee members are appointed by the Minister. Each member is selected because of their relevant industry expertise. This creates a situation where a potential conflict of interest is a common occurrence.

2.20 *The Industry Research and Development Board Members Handbook* (the Handbook) sets out the process for managing a declared potential conflict of interest. Each potential conflict of interest must be declared and classified as either material or immaterial.[40] Any member of the Committee found to have a potential material conflict of interest will not take part in the assessment and merit ranking of that application. Table 2.1 shows the potential conflicts of interest declared by the Committee members in Rounds One and Two of the Program.

Table 2.1

Potential material and immaterial conflicts of interest for Rounds One and Two

Round	No. of applications	Potential material conflicts of interest	Potential immaterial conflicts of interest
Round One	26	51	9
Round Two	11	20	17

Source: ANAO analysis of AusIndustry data

2.21 The most common reason for a Committee member declaring a potential conflict of interest was a shareholding or position in a company, which had an actual or potential connection with the applicant or companies mentioned in the application. In both rounds:

- the decisions made concerning the materiality of potential conflicts declared were documented in accordance with the Handbook; and
- the Probity Advisor found the Committee's decisions on the materiality of each conflict of interest to be reasonable.

2.22 A quorum of at least three Committee members must be present before an individual application can be assessed. This was not possible for one application in Round One because of potential conflicts of interest. As previously noted, in these circumstances, the IR&D Board is required to complete the merit ranking of applications. The two Committee members who did not have a potential conflict of interest assessed this application and provided advice to the Board. The Board then completed the merit ranking process using the Committee's provisional rankings for the other applications.

[40] A material conflict of interest is any connection to an applicant or company mentioned in the application from which a Committee member may derive, or could be perceived to derive a pecuniary benefit.

2.23 Involving the Board is a practical and timely way of completing the assessment process. The members of the Board have experience in assessing the merit of applications for many similar programs and can access the Committee's records and other expert advice. The Committee was able to form a quorum for each application it considered in Round Two.

Offers for grant funding

2.24 In making the decision to offer funding, the Program Delegate took into account the merit ranking provided by the Pharmaceuticals Committee. For each round, there was a clear distinction between successful and unsuccessful applicants. The Program Delegate's decision to offer funding was final and there was no appeal provision for unsuccessful applicants. The ANAO reviewed the Program Delegate's decisions and observed that in both rounds, those applicants offered funding were those assessed as most suitable by the Committee.

2.25 The Minister for Industry, Tourism and Resources announced the successful applicants for each round. In Round One, 11 applicants were offered funding totalling just over $87 million across 179 projects. In Round Two, seven applicants were offered funding totalling nearly $47 million across 95 projects.[41] The grants offered in both rounds ranged from $1.9 million to $10 million.

Conclusion

2.26 Overall, there was a high level of awareness about the Program amongst the pharmaceuticals industry. Processes for assessing the eligibility and merit of applications against the Program's criteria were well documented and effectively implemented by AusIndustry and the Pharmaceuticals Committee. In addition, any potential conflicts of interest for Committee members were properly declared and appropriately managed. Funding was offered to those applicants considered most likely to contribute to the Program achieving its overall objective.

[41] One applicant did not take up the offer of funding.

3. Management of Funding Agreements

This chapter reviews AusIndustry's management of the funding agreements between the Commonwealth and grant recipients. The strategy developed by AusIndustry to manage compliance with the funding agreements is also discussed.

Introduction

3.1 The funding agreement (agreement) signed between a successful applicant and the Program Delegate (on behalf of the Commonwealth) establishes the terms and conditions for receiving funding under the Program.[42] The Program Delegate signed 17 agreements with 18 successful applicants from Rounds One and Two. At the time of the audit, there were 16 current agreements.[43] To assess how these agreements were managed by AusIndustry, the ANAO reviewed the:

- negotiation of agreements following the offer of funding;
- calculation of payments to recipients; and
- management of compliance.

Negotiating the funding agreements

3.2 AusIndustry commenced negotiating the agreements with successful applicants from Round One in April 2004 and from Round Two in April 2005. Funding was offered from 1 July of the same year. Delays in finalising the agreements in both Rounds meant that there were no agreements in place by 1 July in either year. The time taken to negotiate the agreements ranged from 78 to 160 days in Round One and from 154 to 181 days in Round Two. AusIndustry is now required by its Customer Service Charter (published in July 2005) to negotiate all agreements for Round Three within 90 days.

3.3 Delays were generally caused because an applicant's portfolio of R&D projects had changed since the application had been submitted.[44] As a

[42] The funding agreement was developed jointly by AusIndustry's legal team and the Australian Government Solicitor.

[43] One company from Round Two declined to sign an agreement as their circumstances changed. One agreement was terminated in 2006 because the company had not earned a payment and was unlikely to earn any in the future.

[44] Applications were lodged six months prior to the commencement of funding agreement negotiations.

consequence, AusIndustry had to re-confirm the quality of these portfolios.[45] Despite these delays, recipients' access to funding was not affected as payments are made in arrears and all agreements were signed before the first payment was available in October of that year.

Recipient reporting and calculation of payments

3.4 The amount of grant funding offered to recipients was based on the expenditure forecasts for the R&D projects (the portfolio) included in the application. These expenditure forecasts were used to calculate the maximum grant payment a recipient could earn each year.[46] The offer of grant funding made to each successful applicant is the total of these annual amounts (across the period of the agreement). For example, a recipient's forecasts could indicate a maximum annual grant payment of $1 million would be earned in their first year, $3 million in year two and $2 million in year three. If successful, this applicant would be offered grant funding of $6 million. Payments earned are calculated from recipient's reported actual expenditure and are made quarterly, in arrears.

Recipient reporting

3.5 To enable the payment earned to be calculated, recipients are required to submit, for each financial year, three quarterly reports (due at the end of October, January and April) and one annual report (due at the end of August). These reports include:

- actual expenditure on eligible pharmaceuticals R&D activities;
- grant monies received from other government sources; and
- progress made against the milestone(s) identified for each R&D project in the portfolio.

3.6 The quarterly reports provide summary information, such as the total actual expenditure across the portfolio of R&D projects. The annual report provides detailed information on actual expenditure and activity for each R&D project in the portfolio. This information must be substantiated by an audit

[45] The Pharmaceuticals Committee may also provide advice to AusIndustry and the Program Delegate about the quality of changed portfolios.

[46] The maximum annual grant payment is the forecast expenditure less than the ABL multiplied by the refund of 30 cents for every dollar expended.

statement.[47] Failure to submit a report may result in the payment being withheld and the recipient's risk rating being increased. Failure to submit two or more reports may result in the agreement being terminated.

Calculation of the funding payment

3.7 A payment to the recipient is due if the quarterly report includes actual R&D expenditure for that quarter that is greater than one-quarter of the ABL.[48] The payment based on the annual report is a 'balancing' payment. A payment will be due if the recipient's actual expenditure for the entire year exceeds the full ABL and the payment due exceeds the combined total of payments made in any of the previous three quarters. In addition, the payment due to a recipient will be affected by:

- any overpayments that have already been made;
- the recipient receiving other government grant payments; and/or
- underperformance or overperformance in previous years.

3.8 AusIndustry's Grants and Loans Activity Management system calculates the payment due. The agreement describes the formulae for calculating the payment due. The ANAO confirmed that payments were calculated correctly.

Milestone Activity

3.9 As previously noted, recipients are required to report on progress made against the milestone(s) identified for each R&D project in their portfolio. However, this information is not taken into account when calculating payments to recipients. Payments are earned solely on the basis of expenditure above the ABL. A recipient's progress in achieving their milestones is considered as part of the recipient's risk assessment and when managing underperformance.[49]

[47] The audit statement verifies the actual expenditure incurred in the payment year and that the expenditure complies with the Program guidelines. The audit must be performed by either a registered company auditor or an authorised audit company.

[48] The quarterly payment is capped at 25 per cent of the maximum annual grant payment for the first quarter and this capped rate increases to 50 per cent and 75 per cent for subsequent quarters.

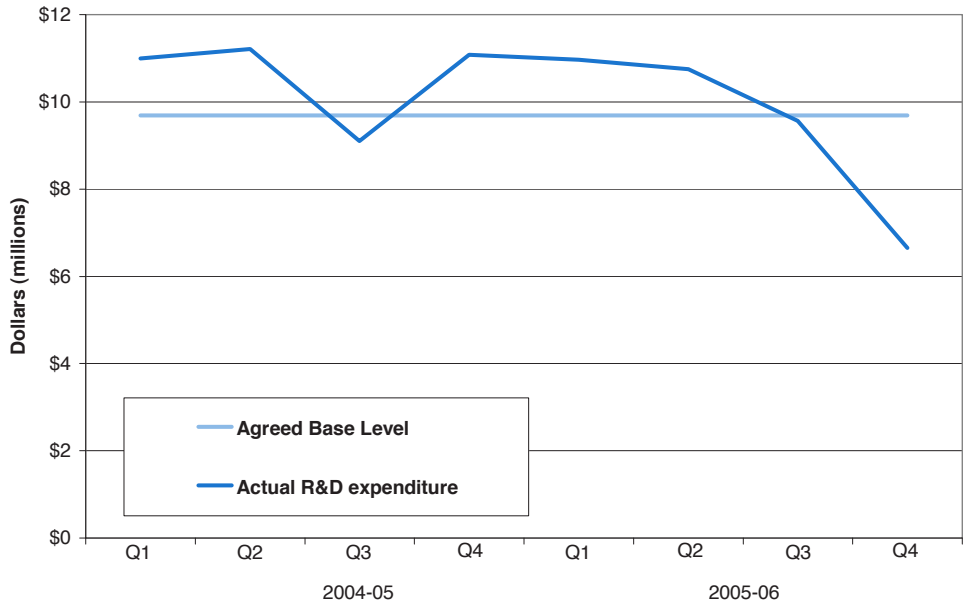
[49] AusIndustry calculates a recipient's annual progress against their milestones by dividing the number of milestones completed by the total number.

Overpayment of funding

3.10 An overpayment can occur when the actual annual payment due is less than the combined total of payments already made, based on the previous three quarterly reports. Figure 3.1 provides details of one recipient's actual expenditure on R&D activities against their ABL for the period 2004–2006. This recipient was overpaid almost $700 000 in 2005–06.

Figure 3.1

One recipient's actual expenditure on R&D projects against the ABL for the period 2004–2006



Source: ANAO analysis of AusIndustry data

3.11 In 2004–05 and 2005–06, six companies were overpaid a total of approximately $1.5 million (nine per cent of total payments earned). The individual amounts varied between $8000 and $700 000. Under the agreement, these amounts must be recovered by AusIndustry. Overpayments, which are able to be recovered, should be accounted for by the department as either a prepayment[50] or a receivable.[51] However, AusIndustry recorded these overpayments as an expense. This practice does not meet Australian

[50] A prepayment is where the overpayment can be offset by subsequent payments as permitted by the agreement.

[51] Where the Program Delegate considers that an overpayment will not be offset within a reasonable period of time, the delegate will declare the amount a debt and AusIndustry will seek repayment within 30 days.

Accounting Standards[52] and financial statement reporting requirements.[53] AusIndustry advised that, in future, all overpayments will be correctly recorded.

3.12 As of March 2007, five companies had offset their overpayments through payments earned. AusIndustry advised that, although the amount of almost $700 000 remains outstanding for one recipient, it is being treated as a prepayment and will be declared a debt at the end of 2006–07 if it has not been offset by then.

3.13 The agreement outlines the circumstances where a payment may be withheld. However, these do not include where an overpayment is likely due to a significant reduction in actual expenditure for any quarter(s). To minimise the potential for overpayments, AusIndustry needs to monitor the pattern of recipients' R&D activity and its effect on actual expenditure and payments. Consideration could also be given to including in the funding agreements of future programs a provision to allow payments to be withheld if there is the potential for an overpayment to occur.

Other government grant payments

3.14 The Program allows recipients to include in their portfolio, projects for which they are also receiving other government grants. This funding is deducted from the payment due to prevent recipients 'double dipping'. During 2004–05 and 2005–06, three recipients received grants from other government programs. In total, this reduced actual payments made by the Program by almost $1.25 million in 2004–05 and by almost $0.4 million in 2005–06.

Recipients' overperformance and underperformance against forecasts

3.15 As discussed previously, funding offered to each recipient is based on their forecast R&D expenditure. In practice, a recipient's actual R&D expenditure can differ considerably from their forecast expenditure. The agreement sets out how to manage overperformance (where actual expenditure exceeds forecast expenditure) and underperformance (where forecast expenditure exceeds actual expenditure).

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[52] Australian Accounting Standards Board 139: *Financial Instruments: Recognition and Measurement*, February 2007.

[53] Australian National Audit Office, *Better Practice Guide-Administration of Grants*, May 2002, p. 60.

3.16 Where a recipient has overperformed, the additional payment earned in that year can be:

- paid out by the Program Delegate from unused financial commitment in that year. The payment is also deducted from the total grant funding set out in the recipient's agreement; or
- used to offset underperformance in the previous year or to offset potential underperformance in future years.

3.17 Where a recipient has underperformed, they are only able to carry unused funding into the next year if the following criteria are met:

- actual expenditure must exceed 75 per cent of forecast expenditure; and
- the payment due must be at least 50 per cent of the maximum annual payment.

3.18 Table 3.1 outlines the number of recipients who underperformed and overperformed in 2004–05 and 2005–06.

Table 3.1

Recipients' underperformance and overperformance in 2004–05 and 2005–06

Details	2004–05	2005–06
Total number of recipients in the Program	**11**	**16**
No. of recipients that underperformed	10	10
No. of recipients that overperformed	1	6

Source: ANAO analysis of AusIndustry data

3.19 In 2004–05, the overperforming recipient was paid almost $380 000 above their maximum annual payment. The six recipients that overperformed in 2005–06 carried their overperformance (a total of almost $7.4 million) into future years of the Program. Of the 10 recipients that underperformed in 2004–05, three were able to carry their funding into the next year. Of the 10 recipients that underperformed in 2005–06, five were able to carry their funding into the following year. The remaining recipients in both years lost access to the unused funding.

3.20 Table 3.2 shows the difference between the original payment forecasts, the forecasts following variations to some agreements and the actual payments earned by recipients in 2004–05 and 2005–06.[54]

Table 3.2

Comparison of forecast and actual payments for the period 2004–05 and 2005–06

Year	Original payment forecast	Post-variation payment forecast	Actual payments
2004–05	$14 724 594	$10 953 146	$ 4 737 959
2005–06	$19 699 570	$18 766 263	$11 478 123
Total	**$34 424 164**	**$29 719 409**	**$16 216 082**

Note: The 2004–05 actual payment value includes an amount of $378 390 paid to the recipient that over performed. Actual payment values in both years exclude overpayments made to recipients.

Source: ANAO analysis of AusIndustry data

3.21 Currently, the Program is considerably underspent. AusIndustry advised that a program is likely to be underspent where the delivery of funding is demand-driven, and particularly where expenditure on R&D is inherently unpredictable. To manage the underspend, funding foregone by recipients in 2004–05 and 2005–06 was made available to Round Three applicants. An overall Program underspend is likely to continue as there are no further funding rounds.

Managing compliance

3.22 Managing a recipient's compliance with their agreement should provide assurance that the grant funding is being used appropriately and that each recipient is meeting the conditions for receiving that funding. AusIndustry intended a high level of compliance monitoring for the Program, given its complexity and the small number of recipients involved. AusIndustry has three mechanisms for managing a recipient's compliance:

- varying the agreement;
- through its Compliance Management strategy; and
- undertaking ad hoc reviews.

[54] Varying the agreement is discussed in paragraphs 3.23–3.25.

Variations to funding agreements

3.23 The Program allows recipients to claim against a portfolio of projects. AusIndustry accepts that there will be some variation at the portfolio level due to projects failing, new projects starting and expenditure forecasts being revised. To address the changing circumstances of recipients, the agreement allows variations to the portfolio.

3.24 Recipients advised the ANAO that their ability to accurately forecast future activity in their application was limited because R&D projects can be delayed or cancelled. When this occurs, the project budget is re-allocated to a new project(s) and a variation to the agreement is sought to:

- substitute a new R&D project with one already in their portfolio; or
- add new R&D projects to the portfolio.

3.25 The recipient must demonstrate that the portfolio's overall quality is maintained and this is assessed by AusIndustry and, when requested, the Pharmaceuticals Committee. The Program Delegate decides whether to approve or reject variations based on their advice. As of October 2006, 16 variations have been requested[55] and these resulted in the addition of 27 projects and the removal of 11 projects. Overall, these variations did not affect the Program's future funding profile. The ANAO considers that varying the agreement is a practical way of addressing the difficulties recipients have in forecasting their R&D projects and expenditure.

Compliance Management strategy

3.26 AusIndustry has implemented a Compliance Management Strategy to monitor recipient compliance with their agreements. The strategy sets out the:

- basis for determining a recipient's risk rating;
- activities to be undertaken at each compliance level; and
- number of activities (targets) that will be undertaken annually for each compliance level.

Determining recipients' compliance risk ratings

3.27 A recipient's compliance risk rating is assessed against the risk criteria outlined in the strategy. All recipients entering the Program are rated as a 'low'

[55] Of these: 10 requests were approved and executed; two requests were approved but not executed, two requests were awaiting a decision, and a further two requests were withdrawn or rejected.

compliance risk.[56] This risk rating is revised as necessary after the quarterly and annual reports have been evaluated. The ANAO reviewed the recipients' compliance risk ratings for 2004–05 and 2005–06, and found the ratings were not always consistent with the risk criteria in the strategy. For example, in six instances, AusIndustry did not apply a 'high' rating although the risk criteria for this rating had been met. As a consequence, recipients may have received a lower level of compliance monitoring.

3.28 AusIndustry advised that, at the time of applying the lower rating, it was aware that variations to agreements had been submitted for three recipients, although only one had been executed.[57] AusIndustry also took into consideration additional information provided by the other three recipients.[58] Apart from the variation that had been executed, none of these companies had adequately demonstrated that the risks had been mitigated at the time the ratings were assessed. In the ANAO's view, the higher rating should have been applied until the actions proposed by the recipients had addressed any perceived risks.

3.29 AusIndustry advised that it also considered a recipient's ability to earn further payments when assigning some recipients a risk rating that was higher than required by the strategy. This risk indicator is currently not part of the strategy's risk criteria. To ensure a comprehensive approach, all criteria used by AusIndustry to assess recipients' compliance risks should to be included in the strategy.

Levels of compliance activity and compliance targets

3.30 The strategy has four levels of compliance activity, which are outlined in Figure 3.2. Monitoring activities are primarily company visits and evaluating recipients' quarterly and annual reports. The strategy also outlines the number of activities (or targets) to be undertaken annually for each compliance level. AusIndustry provide monthly reports to its Executive Committee on the activities undertaken.

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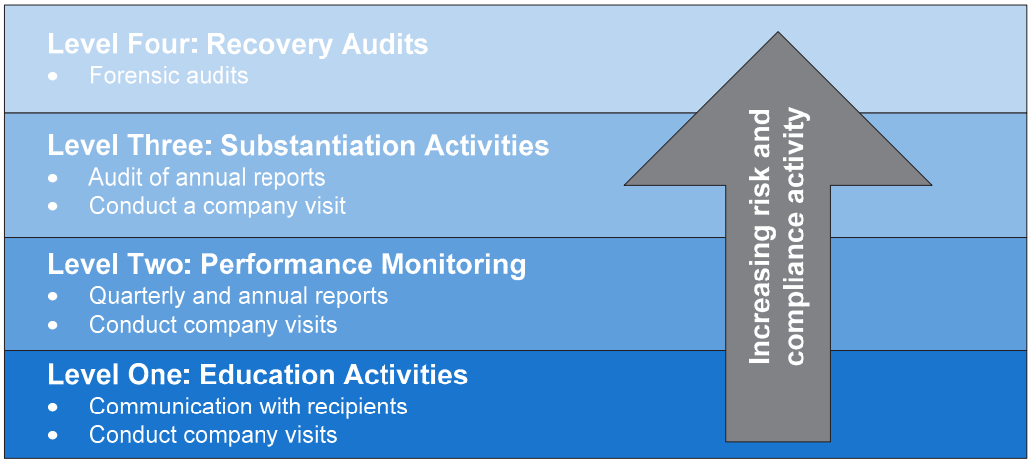
[56] The rationale for this rating is that recipients have passed through the merit assessment process prior to signing the funding agreement.

[57] A variation is executed when the funding agreement is changed to incorporate the proposed changes into the portfolio. A second variation was executed in December 2005 but the third variation was never executed.

[58] For example: one recipient intended varying their agreement; another was completing a strategic review of its research priorities; and the other provided information about a new development in one of their major projects.

Figure 3.2

Four levels of compliance management activity



Source: ANAO analysis of AusIndustry data

Recipient visits

3.31 Compliance visits are designed to minimise compliance and fraud risks and to provide AusIndustry with a better understanding of the recipient's portfolio. The visits also give recipients the opportunity to discuss reports and to raise any issues. Although the strategy does not clearly define the activity to be undertaken as part of a company visit, AusIndustry advised that the purpose of the visits are to:

- assist recipients to understand their reporting obligations under the Program (Level 1);
- substantiate a recipient's ability to undertake their projects (Level 2); and
- examine a recipient's information and accounting systems (Level 3).

3.32 The Program's operating procedures and the strategy indicate that at least one visit will be made to each recipient from Rounds One and Two in the first two years of the Program. Table 3.3 outlines the targets set for compliance visits and those conducted by AusIndustry for the period 2004–2006. Although the targets were largely met for 2005–06, no visits were undertaken in 2004–05.

Table 3.3

Compliance visit targets and actuals for the period 2004–05 and 2005–06

Visit	2004–2005		2005–2006	
	Target	Actual	Target	Actual
Level 1	0	0	7	6
Level 2	11	0	4	3

Source: ANAO analysis of AusIndustry data

3.33 As of March 2007, only three of the 11 recipients from Round One had received a compliance visit from AusIndustry whereas all six Round Two recipients have been visited. To date, there have been no Level Three visits or forensic audits.

Quarterly and annual reports

3.34 A recipient's compliance is regularly monitored through their quarterly and annual reports. These reports are assessed for:

- consistency between the information reported and previous reports received; the company's annual reports and information on their website; media reports; and discussions held with Innovation Division;
- progress against project milestones and forecast expenditure; and
- accuracy including declarations and evidence of compliance.

3.35 All necessary reports were lodged by recipients. Of the 101 reports due, 52 were received on or before the due date. All other reports were received within 30 days of the due date. The annual report includes an audit statement verifying the actual expenditure and that the expenditure complies with the Program guidelines. In addition, recipients are required to declare that information in the reports is true and correct. Following the evaluation of the annual reports each recipient's risk rating is reviewed and, if necessary, revised.

Setting compliance targets

3.36 The recipients' risk ratings determine the extent of monitoring activity to be undertaken for the Program. These ratings should also be the basis for setting annual compliance activity targets. However, this currently does not occur. AusIndustry advised that the compliance targets are set based on previous outcomes and Program developments.

3.37 The strategy is updated annually in April/May (in preparation for the next financial year). The compliance targets set at this time should be based on the recipients' risk ratings and revised if these ratings change. This will ensure that the activities being undertaken are addressing current and emerging risks.

Conclusion

3.38 Compliance activities are designed to address the level of risk the recipients present to the Program. To date, compliance activities have primarily involved visits to recipients and evaluating their quarterly and annual reports. All reports were submitted and evaluated however, not all planned visits were completed. To enable a complete assessment of recipients' risks, all criteria used by AusIndustry in the risk assessment process should be included in the strategy. Compliance targets should also be based on recipients' risk ratings and revised when the ratings change.

Recommendation No.1

3.39 To enable compliance monitoring activities to address the current risks posed by recipients to the Program, the ANAO recommends that AusIndustry:

(a) include in its Compliance Management Strategy all criteria to be used in assessing compliance risks; and

(b) base compliance targets on recipients' risk ratings and revise targets as necessary when risk ratings change.

DITR's response

3.40 Agreed. DITR will continue to set its Program Compliance Strategy targets in April/May/June (inline with Corporate reporting requirements) and will revise progress in October/November based on the evaluation of recipients' Annual Reports. Further, the Strategy will be revised to include additional guidance on how 'information on-hand' is to be treated in combination with the existing financial triggers when assessing specific risk ratings.

Ad hoc reviews

3.41 The Program's operating procedures and funding agreements allow an ad hoc review to be conducted when a recipient's annual report shows[59]:

- actual expenditure is less than their ABL;
- the annual payment is less than 75 per cent of the forecast payment; or
- milestones have not been met to a sufficient degree.

3.42 As part of the review, AusIndustry staff and members of the Pharmaceuticals Committee will meet with recipients and examine documents and responses to information requests. Possible outcomes from the review are:

- the substitution of eligible R&D projects and amendments to milestones;
- reductions in forecast expenditure, (and therefore payment(s)); or
- termination of the agreement.

3.43 In 2005–06, AusIndustry conducted two ad hoc reviews, which resulted in both recipients requesting variations to their agreements. The ANAO's analysis of the financial information, reported by recipients in their annual reports, indicated that a further four recipients had also triggered a review. AusIndustry advised that these recipients were not reviewed because three had requested variations to their agreements and it was satisfied that the remaining recipient was able to address its performance problem. This recipient also received a compliance visit from AusIndustry in March 2006 as their progress against milestones continued to be poor.

3.44 AusIndustry identified five recipients for ad hoc reviews in 2006–07. The ANAO identified an additional five recipients that also met the requirements for a review. AusIndustry advised that, following the Program's mid-term review[60], it determined that the reviews were not warranted as:

- two of these recipients will be required to substantiate their ongoing participation in the Program as part of a compliance visit in 2006–07; and
- another two recipients have requested variations to their agreements.

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[59] *Pharmaceuticals Partnerships Program Funding Agreement*, Clause 8.2 (c).

[60] The performance of all recipients was reviewed during the mid-term review conducted at the end of 2006.

The remaining recipient will not have any compliance action taken because the company had 'almost reached' its ABL.[61] This is the same recipient that was overpaid almost $700 000 and has yet to earn a payment in 2006–07 to offset this amount.[62]

3.45 Ad hoc reviews were part of the Program's Compliance Management Strategy for the first year of the Program (2004–05) but were removed in later years. As an ad hoc review is a compliance activity, the ANAO considers that, in any future programs, the review should form part of the strategy. Acceptable alternatives to a review should, ideally, be identified in the strategy and the Program's operating procedures. Also, where a review is triggered but not conducted, there would be benefit in AusIndustry re-assessing the need for a review following receipt of the recipient's next quarterly report. This would alert AusIndustry to any ongoing compliance matters.

[61] The company had spent 94.7 per cent of its forecast expenditure.

[62] This overpayment is discussed in paragraph 3.12.

4. Governance Arrangements

This chapter reviews the governance arrangements in place for the Pharmaceuticals Partnerships Program. Planning, risk management and performance reporting are discussed.

Introduction

4.1 Effective governance arrangements assist an organisation achieve its overall outcomes in a way that enhances confidence in the organisation, its decisions and its actions.[63] In reviewing the governance arrangements supporting the Program, the ANAO examined the department's:

- planning framework, including its risk management strategy;
- performance management framework; and
- internal and external reporting of the Program.

Planning process

4.2 Effective planning will help to ensure that the Program achieves its objectives. These objectives should be compatible with the agency's outcomes. AusIndustry is responsible for delivering more than 30 products, programs and services to Australian industry. To ensure these are delivered consistently, the *AusIndustry Business Plan* provides high level direction, including performance indicators and milestones. The plan sets out AusIndustry's Key Goals.[64]

4.3 These high level directions are incorporated into the specific product plans for each program. A Product Plan has been produced for each year of the Program. This plan documents the relationship to the AusIndustry Business Plan, particularly for performance management, risk management and compliance and fraud strategies. The Plan also details how these will be managed at the program level.

4.4 AusIndustry's planning documents are comprehensive and outline the responsibility and reporting requirements at each level. There are also clear linkages between all plans. The plans are updated at least annually and more

[63] Australian National Audit Office, *Better Practice Guide-Public Sector Governance*, August 2003, p. 6.

[64] These goals are program delivery, risk management and accountability, developing and supporting our people and, business support systems.

frequently if changes impact on a program. The planning documents provide a structure for activity to be reported monthly and quarterly to AusIndustry's Executive Committee and monthly at the department's Portfolio Managers' Meeting.

Risk management

4.5 AusIndustry's risk management framework supports the delivery of the Division's fundamental role, which is *delivering the policy objectives of each of our programs.* This framework consists of a series of related plans. These include the:

- **AusIndustry Risk Management Plan,** which describes the risks to AusIndustry delivering against its fundamental role[65];
- **AusIndustry Risk Priorities for Programs,** which compares risks across all programs based on the number of stakeholders, the program's dollar value and the complexity of the program; and
- **Program Risk Management Plan,** which describes the risks to the Program against each of the five Key Risk Areas (KRAs): financial management; program outcomes and objectives; service delivery; program governance; and compliance management.

Program risks

4.6 The Program has been assessed as a 'moderate' risk when compared with all other AusIndustry programs. However, at the individual program level, the Program has been rated consistently as a 'high' risk because of underperformance against the financial management KRA. The current strategies to treat this financial risk include: carrying forward recipients' underperformance; re-phasing expenditure into future years; re-allocating funding to recipients in the final round; and/or paying out a recipient's overperformance.

4.7 The ANAO's analysis of AusIndustry data has shown that the total payments made were almost 60 per cent and almost 40 per cent less than recipients had forecast for years one and two respectively.[66] The data analysis

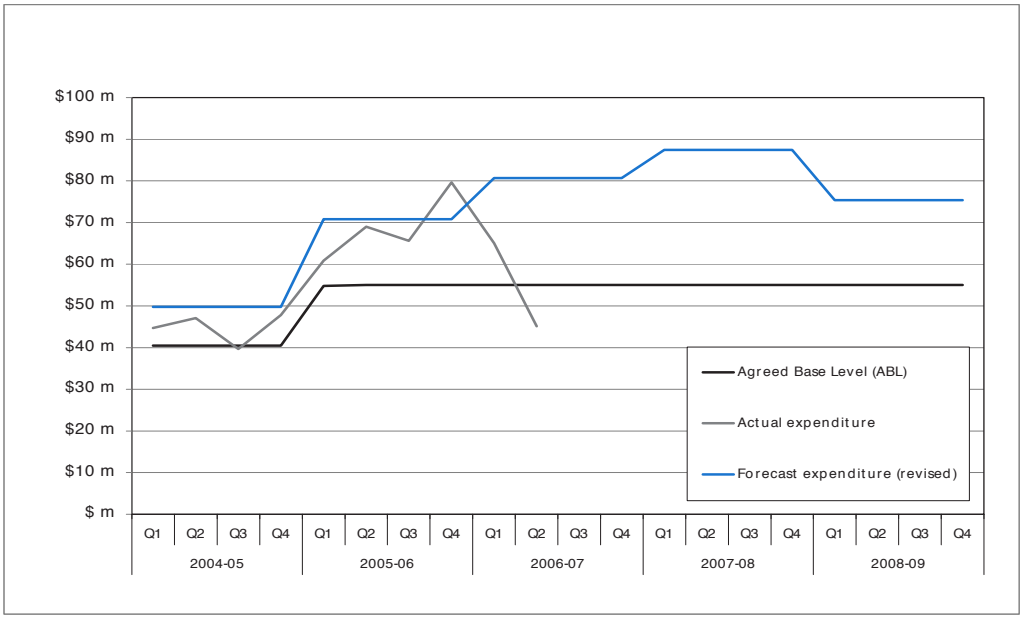
[65] For example, a failure of operational procedures in programs is considered a 'high' risk.

[66] In 2004–05, the original forecast of $14.7 million was revised to $11 million, with actual payments of $4.7 million being made. In 2005–06, the original forecast of $19.7 million was revised to $18.8 million with actual payments of $11.5 million being made.

also indicates that forecast expenditure for the Program, based on recipients' forecasts, has increased markedly for the final three years of the Program. The current treatment strategies are compounding this effect as they are moving underperformance (against expenditure) and appropriations into the remaining years. Figure 4.1 illustrates this trend and outlines the recipients' forecasts for 2004–05 to 2008–09 and their actual expenditure for 2004–05, 2005–06 and quarters one and two of 2006–07. The actual expenditure for quarter two of 2006–07 does not include the expenditure for three recipients that are currently varying their contracts.

Figure 4.1

Program recipients' actual expenditure by quarter, compared to their agreed base level and revised expenditure forecasts1



Note 1: The actual expenditure for quarter two of 2006–07 does not include the expenditure for three recipients that are currently varying their contracts.
Source: ANAO analysis of AusIndustry data

4.8 The expenditure forecasts and payments are for Round One and Two participants who will be in the Program for a minimum of four years. The increase in the ABL for 2005–06 reflects the inclusion of Round Two recipients from July 2005. In the third quarter of the first year of the Program (2004–05), the total of recipients' expenditure was marginally less than the total of the ABL. In the fourth quarter of the second year (2005–06), recipients expenditure was higher than forecast.

4.9 Innovation Division and AusIndustry consider that the Program has a number of features to manage the risks associated with providing incentives for companies to undertake high quality, but volatile pharmaceuticals R&D. Companies who underspend in any given year are not able to automatically recoup this money in future years, they must seek the Delegate's approval to vary their forecast activity. Similarly, in the first two rounds of the Program, participants were only able to carry forward underperformance for 12 months.

4.10 These provisions were much tighter than those that existed under the previous Pharmaceutical Industry Investment Program, which allowed participants to carry over underperformance for up to four years. The mid-term review also provides an opportunity to revise all participants' forecast activities in light of their actual activity. If necessary, AusIndustry is able to reduce participant's future forecast activity levels and future payments. The Program also has three funding rounds to allow monies to be reallocated to new participants and to minimise a likely Program underspend.

Risks associated with recipients

4.11 The capacity of the Program to achieve its objectives is entirely dependent on the success of a small number of recipients completing their additional R&D activity. The current Program Risk Management Plan identifies a number of risk categories but does not identify recipients' performance as a major source of risk although some of the mitigation strategies are directed at recipients. AusIndustry advised that the recipients' compliance risk ratings are considered collectively when assessing the Program's risks. However, it was unable to show how these ratings are considered. For Program risks to be effectively managed, recipients' performance need to be identified as a major source of risk and any analysis of recipients' risks documented and incorporated in the Program Risk Management Plan.

Recommendation No.2

4.12 To provide a comprehensive assessment of the risks facing the Pharmaceuticals Partnerships Program, the ANAO recommends that AusIndustry, in its Program Risk Management Plan:

(a) includes recipients' performance as a major source of risk; and

(b) reviews current strategies for mitigating identified risks.

DITR's response

4.13 Agreed. DITR currently includes the collective financial impact of grant recipients' risks when reporting on program performance. For example, when one or more recipient payment slippages result in a program financial variance of greater than 10 per cent. DITR will review current risk mitigation strategies in relation to Recommendation No. 1.

Performance management

4.14 An appropriate performance management framework should enable the department to monitor and measure the Program's progress towards achieving its objectives. The Program's overall objective is *to increase the level of high quality pharmaceuticals R&D undertaken in Australia*.[67] The Program also has the following sub-objectives:

- promoting additional, high quality R&D across the pharmaceuticals industry above what would have been done in the absence of the Program;
- encouraging the development of medicines for global markets; and
- encouraging partnerships and linkages between multinational firms and local players.

Outcome and outputs framework

4.15 The Program is funded under the department's Outcome One. All administered programs within this Outcome, including the Pharmaceuticals Partnerships Program, fall within Output Group 1.1, Program Management Services. These programs are aggregated for external reporting against administered and departmental quality, quantity and price indicators.[68]

4.16 The *Business Partnership Agreement between Innovation Division and AusIndustry* (BPA) outlines performance information collection and reporting responsibilities. Innovation Division monitors and evaluates the appropriateness, efficiency and effectiveness of the Program. The Division may also collect additional data to assist with evaluating the Program. AusIndustry provides information to assist Innovation Division to report against the agreed intermediate performance outcome indicators (or sub-objectives). Information

[67] *Business Partnership Agreement between Innovation Division and AusIndustry*, 4 October 2004.

[68] Indicators include: the percentage of customer and stakeholder satisfaction; the results of program evaluations; the number of programs managed; and the total cost of programs managed.

is collected against the BPA's key performance indicators (KPIs) outlined in Appendix 2. These indicators are designed to enable:

- monthly and quarterly reporting to the AusIndustry Executive Committee against the KRAs and the progress being made towards achieving the Program's objective and sub-objectives; and
- information to be collected to support the future evaluation of the Program.

Industry baseline data

4.17 For the department to assess if the Program is achieving its overall objective, industry-wide baseline data on the expenditure and quality of R&D activities needs to be available and monitored from the commencement of the Program.

4.18 The Pharmaceuticals Committee has determined, through the merit assessment process, that the R&D activity being undertaken as part of the Program *is consistent with the Program's objective of increasing the amount of high quality R&D undertaken in Australia*. The industry-wide data being collected for the Program does not address the quality of R&D activity being undertaken. Consequently, there is no baseline data available to assess whether an increase in the level of pharmaceuticals R&D being undertaken is of the same quality required by the Program.

4.19 The department collects biennial expenditure data for pharmaceuticals R&D activity in Australia from the Australian Bureau of Statistics.[69] It has recently been advised that this information is available annually and will now use the 2003–04 data as the baseline to measure the increase in industry-wide R&D activity generated by the Program.

Recipients' performance data

4.20 Recipients are required to provide, in their annual reports, performance information relating to the Program's three sub-objectives. This includes: the commercialisation of research; R&D collaborations and contract research; and actual expenditure. AusIndustry collects this data on behalf of Innovation Division. AusIndustry reports expenditure data internally but commercialisation and collaborations data is not reported by either

[69] R&D statistics were collected annually for business and biennially for higher education, general government and private non-profit organisations.

AusIndustry or Innovation Division. Innovation Division advised that this information may be used for policy development, when providing advice to the Minister and for future evaluations.

4.21 Currently, the commercialisation and collaborations performance data is not stored electronically. The ANAO has been advised that there are fields for this data in AusIndustry's Grants and Loans Activity Management database, and suggests that the information be captured and stored in this database. This will allow Innovation Division easier access to, and enable ongoing analysis of, the data.

Limitations of commercialisation and collaboration data

4.22 Commercialisation information relates to patent applications, licensing arrangements and the registration of products. A benchmarking study conducted under the industry Action Agenda details a timeline that shows that the first four stages of R&D may take 6–10 years, with registration an additional 2–3 years.[70] Given this timeframe, it is highly likely that the registration data provided will be for projects that existed before the Program commenced. The agreements allow for information to be collected from recipients for up to five years after the recipient's exit date. Collecting this information post exit will provide a more accurate reflection of the Program's impact. The department may wish to consider whether this is a reasonable indicator for future programs, given the extended timeframes involved.

4.23 Information relating to partnerships and collaborations is reported by Program participants; however this information is not validated. Applicants in Rounds One and Two were requested to provide details of existing and intended collaborations and partnerships as part of their applications but they were not required to provide evidence to support their claims. Round Three applicants have been required to provide documentation giving details of intended partnerships and collaborations.[71]

R&D expenditure data

4.24 The department considers that actual expenditure above the ABL is the best indicator of additional R&D activity. Although the department recognises that this is not a definitive measure, it is a practical way of assessing

[70] Economist Intelligence Unit, *Benchmarking Study of the Characteristics of the Australian and International Pharmaceuticals Industries,* September 2005, p. 15.

[71] This may include letters of intent, draft agreements or memoranda of understanding from potential partners or collaborators describing the nature, timing and scope of the arrangements.

additionality across a portfolio of projects. To gain a better understanding of the level of additionality being undertaken, the ANAO interviewed seven[72] of the 16 current Program participants. Five of these participants indicated that the R&D they were undertaking would have occurred without Program funding, although in some instances it may have taken longer to complete some of the activities.

4.25 The ANAO also analysed AusIndustry data to determine what could be considered 'additional' R&D activity conducted by recipients up to 31 December 2006.[73] Table 4.1 outlines total R&D expenditure, expenditure above the ABL and payments for the Program for 2004–05 and 2005–06.

Table 4.1

R&D expenditure, expenditure above the ABL and payments for the period 2004–05 to December 2006

Year	Total expenditure on R&D activity $ million	Expenditure above the ABL $ million	Payments $ million
2004–05	179.0	15.8	4.7
2005–06	275.0	38.3	11.5
Total	**454.0**	**54.1**	**16.2**

Source: ANAO analysis of AusIndustry data

4.26 The total payments made in the first two years of the Program were $16.2 million. This data indicates that, although there has been an increase in R&D activity of $54.1 million, the Program is considerably underspent against its allocation of $150 million.[74] An additional $6.7 million was paid to recipients for activity conducted between 1 July 2006 and 31 December 2006. However, this figure does not include possible payments for three recipients who are currently varying their contracts.

4.27 As industry-wide comparison data is now available for each year of the Program, the department is in a position to progressively measure and report the increase in industry-wide R&D activity annually. However, it will not be able to readily assess whether the increase meets the expected 'high quality' standard.

[72] The ANAO interviewed a cross-section of recipients based on the size and type of the organisation.

[73] This is the most recent available data from AusIndustry.

[74] Of this figure, $10 million has been transferred to the Mammalian Cell Research Facility.

4.28 Table 4.2 outlines the increase in R&D expenditure for both the industry and Program's participants for the first year of the Program (2004–05).

Table 4.2

Increase in R&D expenditure for industry and Program participants in 2004–05

Expenditure	2003–04 $ million	2004–05 $ million	Increase $ million	Percentage Increase
Industry-wide expenditure	571.3	643.0	71.7	12.6
Program participants' expenditure (based on ABL)[1]	163.2	179.0	15.8	9.7

Note 1: The ABL is based on an average of expenditure for the three years prior to the commencement of the Program. As previously noted the department used the ABL as the mechanism to determine 'additional' R&D activity.

Source: ANAO analysis of DITR data

4.29 This data indicates that, for the first year of the Program, the increase in R&D expenditure by recipients was broadly in line with the growth in R&D expenditure industry-wide. Expenditure industry-wide increased by 12.6 per cent and by 9.7 per cent for the Program's participants. In 2005–06, there was a considerable increase ($38.3 million) in additional R&D expenditure by the Program's participants.[75] However, industry data is not yet available to enable a comparison to be made.

Performance reporting

External reporting

4.30 Agencies and the Government fulfil their accountability requirements to Parliament and the public through external Outcome, Output and program reporting. If specific program reports are not made available this accountability is usually achieved through detailed information in departmental annual reports.

4.31 Reporting of all AusIndustry Output One programs, including this Program, are aggregated in the department's annual reports. The IR&D Board's annual report provides some information on activities the

[75] Refer Table 4.1 for participants' total expenditure on R&D activity.

Committee carries out in relation to the Program. For example, the number of applicants assessed in a round and the number of interviews conducted. The number of successful recipients and the amount of funding offered is also reported. The department's 2005–06 Annual Report only mentions that the Program is an innovation program, that changes were made to the merit criteria for Round Three and when the Round would commence.[76] The department will now be able to report the ongoing increase in additional R&D expenditure for the Program.

Internal reporting

4.32 Program information is reported to AusIndustry's Executive Committee monthly and quarterly. Monthly reporting is against the five KRAs.[77] Quarterly reviews cover a longer term view of the KRAs and also include Program outcome performance indicators, governance and progress against the Product Plan. Exception reports for programs that are not on track are then produced for the department's Executive.

4.33 Monthly and quarterly reports provided to the Committee for both years of the Program were reviewed. The monthly reports primarily focus on program delivery with indicators covering: the number of applications in a Round; the number of successful applicants; and the time taken to negotiate agreements. While these indicators are useful for assessing the quality of AusIndustry's service delivery and the quantum of activity undertaken, they do not measure the progress being made towards achieving the Program's objective or sub-objectives.

4.34 Quarterly reports list outcome performance indicators such as: additional R&D expenditure; the number of new collaborations, and the number of pharmaceuticals that reach product registration. As previously noted, AusIndustry collects this information on behalf of Innovation Division. However, with the exception of expenditure data, this information is not reported within the department but will be used when evaluating the Program.

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[76] Department of Industry, Tourism and Resources, *2005–06 Annual Report,* pp. 3, 23 and 65.

[77] The KRAs are: financial management; program outcomes and objectives; service delivery; program governance; and compliance management.

Conclusion

4.35 A full understanding of performance can only be obtained through a complete set of performance indicators. Generally, more than one indicator is required to measure a Program's effectiveness, quality, quantity or cost. Where the Program has a longer-term objective, progress can be measured through intermediate or sub-objectives.

4.36 Currently, there is no ongoing assessment of whether the Program is meeting its overall objective or two of its sub-objectives. Performance data is collected for all Program sub-objectives, but only expenditure data is reported within the department. The information relating to collaborations and commercialisation of research is collected annually but will not be used until the Program is evaluated. Capturing this information electronically and validating intended collaborations and partnerships in Round Three will put the department in a better position to analyse and report the Program's ongoing performance against all sub-objectives.

4.37 Industry-wide expenditure data is now available to the department annually and will enable an ongoing assessment of the increase in R&D activity generated by the Program. This information should be reported internally and externally. However, the quality of R&D activity is only known for Program participants.

Evaluating the Program

4.38 The Program ceases on 30 June 2009 and the department is committed to evaluating the Program in the first half of 2007–08. The Program was reviewed by the department's internal auditors and the Centre for International Economics in 2005 (after the first year of the Program's operation). The internal audit of the Program was based on a small sample of recipients[78] and found that governance arrangements represented good practice, handling of agreements was appropriate and that Program risks had been appropriately addressed.

4.39 The Centre for International Economics review included a survey of successful and unsuccessful Program applicants and a cross section of pharmaceuticals companies that did not apply for the Program. The review found that the Program was highly regarded, although the level of impact was minor. There was a small net positive contribution to the Australian economy

[78] A sample of three successful and three unsuccessful applicants was chosen.

in the first year of the Program of approximately $30 000.[79] Actual R&D expenditure was almost half the amount forecast by recipients. The review suggested that a longer timeframe would provide a more accurate assessment of the Program's impact as participants had only completed the first year of their five year agreements.

Proposed 2007–2008 program evaluation

4.40 The department intends measuring the Program's performance for Rounds One and Two against its overall objective and the following indicators:

- increase in pharmaceuticals R&D activity undertaken in Australia;
- number of multi-national firms with regional or global operations in Australia;
- number and quality of linkages within the industry and international engagement of Australian companies;
- quality of R&D undertaken; and
- level of benefit to the Australian economy.

4.41 The evaluation will also consider the level of additional activity that has been generated by the Program, that is, the activity that would not have occurred in the absence of the Program. Currently, participants are not required to identify the additional activity they are undertaking.

4.42 As there is a small number of participants in the Program, the ANAO suggests recipients be asked to identify the additional R&D activity they have undertaken through the Program, as they were in the previous Program evaluation. They could also be requested to provide documentation to support any new partnerships and collaborations developed as a result of the Program. As previously discussed, this information was not validated for Rounds One and Two.

4.43 The evaluation will cover Program expenditure data from 2004–05 to 2006–07. Complete Program data may not be available for 2006–07, if any proposed variations to the funding agreements have not been executed by the time the evaluation is conducted. The department has advised that they will use the information submitted by companies on the basis that it will be provisional.

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[79] The model used to estimate the net positive contribution was based on a range of assumptions from the evaluation survey results and recipients' annual reports. Centre for International Economics, *Pharmaceuticals Partnerships Program First year evaluation,* 27 February 2006.

4.44 The current timing of the evaluation will allow the department to include information from Round Three relating to:

- the number and type of successful companies, including new entrants to the Australian market;
- the amount of funding offered;
- details of proposed collaborations and partnerships, which is to be verified for the first time in this Round; and
- whether the increase of the refund payment to 50 cents in the dollar was a significant factor for applicants.

4.45 The proposed Program evaluation will measure some important aspects of the Program but it will be difficult to deliver a complete assessment on whether the Program's overall objective is being met because of the lack of industry-wide data on the quality of the R&D activity being undertaken.

Lessons for future R&D assistance programs

4.46 The ANAO has raised a number of issues in relation to the performance information being collected to measure whether the objective and sub-objectives of the Program have been achieved. The lessons from this Program will be valuable for the department when designing future R&D assistance programs. For example, when implementing a new program it is important that:

- the desired outcomes for the program, including any intermediate outcomes, are clearly specified and able to be measured;
- the original planning for a program needs to take account of future evaluations and develop relevant and reliable performance indicators as a basis for these evaluations;
- the performance information to be collected and how it will be analysed and reported should be determined at the commencement of the program;
- appropriate baseline performance information and how it will be collected and analysed is identified at the commencement of the program;
- recipients be asked to validate and report any activity that will be used to assess whether a program is achieving its objective; and

- where milestones are to be used as a measure of activity, progress against these should be reported consistently across the program, by recipients.

Ian McPhee
Auditor-General

Canberra ACT
20 June 2007

Appendices

Appendix 1: Agency Response

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Ms Barbara Cass
Executive Director
Performance Audit Services Group
Australian National Audit Office
GPO Box 707
Canberra ACT 2601

Dear Ms Cass

I refer to your letter of 27 April 2007, concerning the Australian National Audit Office (ANAO) draft report on the management of the Pharmaceuticals Partnerships Program (the Program).

The Department of Industry, Tourism and Resources is pleased with the ANAO's conclusion that "the Program is being managed effectively by the department" and that "the Program is supported by a sound governance framework".

The Department accepts the recommendations for the management of the Program. The adoption of minor improvements in the compliance management of recipients and their individual risk assessment will strengthen the delivery of the program.

The Department's response to the recommendations and comment on the report are provided at Attachments A and B. A summary of our response to be used in preparation of the audit report and brochure is provided at Attachment C.

I acknowledge the ANAO's cooperation during the audit and the assistance provided to the department.

Should you have any further queries in relation to this response, please contact Ms Judith Zielke, General Manager, Innovation and Collaboration, AusIndustry on 02 6213 7330.

Your sincerely

Mark I Paterson

25 May 2007

Attachment A

ANAO Performance Audit - Management of the Pharmaceuticals Partnerships Program DITR Response to the Recommendations

Recommendation No. 1

To enable compliance monitoring activities to address the current risks posed by recipients to the Program, the ANAO recommends that AusIndustry:

(a) include in its Compliance Management Strategy all criteria to be used in assessing compliance risks; and
(b) base compliance targets on recipients' risk ratings and revise targets as necessary when risk ratings change.

DITR response

Agreed. DITR will continue to set its Program Compliance Strategy targets in April/May/June (inline with Corporate reporting requirement) and will revise progress in October/November based on the evaluation of recipients' Annual Reports. Further, the Strategy will be revised to include additional guidance on how 'information on-hand' is to be treated in combination with the existing financial triggers when assessing specific risk ratings.

Recommendation No. 2

To provide a comprehensive assessment of the risks facing the Pharmaceuticals Partnerships Program, the ANAO recommends that AusIndustry, in its Program Risk Management Plan:

(a) includes recipients' performance as a major source of risk; and
(b) reviews current strategies for mitigating identified risks.

DITR response

Agreed. DITR currently includes the collective financial impact of grant recipients' risks when reporting on program performance. For example, where one or more recipient payment slippage results in a program financial variance of greater than 10 per cent. DITR will review current risk mitigation strategies in relation to Recommendation No. 1.

Appendix 2: Program Specific Performance Measures

AusIndustry
Quantity: Monthly information (available to both AusIndustry and Innovation Division through AusIndustry product performance reports) on program outputs including where possible: • Financial management information, including financial position and variance with expectation; • Service delivery information including number of customers, timeliness against service targets and complaints; and • Risk and compliance information including number of activities undertaken and issues arising, including legal issues.
Quantity: Customer examination and decision process • Total number and value (by level of additional R&D proposed) of total applications received and those that are successful by: – Australian biotechnology companies; – Local subsidiaries of multinational pharmaceutical companies; – Australian pharmaceutical companies; and – other companies (including contract research organisations, service providers, etc). • Number of successful participants in total by type and size of company (for this purpose, a small company has turnover less than $5 million, a medium company has turnover between $5 million to $50 million, and a large company has turnover in excess of $50 million). • Time taken for applicants to prepare an application form
Measures that AusIndustry will collect annually from participants' annual reports
Quantity: The increase in pharmaceuticals R&D activity undertaken in Australia, including the amount and type of new activity taking place in Australia (outcome measure), by participants and type of R&D.

Quantity: The number and quality of linkages within the industry and international engagement of Australian companies (outcome measure) as represented by the:

- Number of eligible R&D collaborations and contract research undertaken in the year prior to entering the Program; and
- Number of eligible R&D collaborations and contract research, identifying which ones are new.

Quantity: Commercialisation of research

- Number of new provisional and full patent applications filed in Australia, the USA or in another jurisdiction by participants relating to research that is either, in whole or in part, supported by the program
- Number and value of licensing deals signed by participants that relate to research that is either, in whole or in part, supported by the program
- Number of products registered with the TGA or equivalent regulatory body that were either, in whole or in part, supported by the program

Quality: Ongoing Customer Management Process

- Proportion of participants who meet their annual quantitative investment targets
- Proportion of participants who meet their annual activity milestones
- Number of ad-hoc performance reviews
- Number of complaints handled
- Number of complaints satisfactorily resolved within the timeframes set out in the AusIndustry Service Charter
- Number and value of payments processed

Cost: Information on the administration cost of customers and funds administered

- Total cost of program delivery and cost per unit

Quality: Information on the quality of service delivered on a periodic basis

- Extent of customer satisfaction with the quality of service delivery

Innovation Division
Quantity: Information on the quantity of policy services delivered (including number and trends over time and per cent of benchmark) on a quarterly basis
Cost: Information on the cost of policy services on a quarterly basis including trends over time and per cent of benchmark or target
Quality: Information on the quality of policy services delivered on a periodic basis for: • Level of compliance with the Departmental Service Charter; • Consultation on policy issues and provision of reasonable time frames for responses to policy proposals as appropriate; • Critical data and information, which has implications for program delivery, provided to AusIndustry without delay; and • Provision of high quality policy advice to Minister and other relevant stakeholder (rating as effective or above) within reasonable timelines.

Source: *Pharmaceuticals Partnerships Program of the Business Partnership Agreement between Innovation Division and AusIndustry 4 October 2004*, 'Policy' Division Program Schedule 1.

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