The Auditor-General

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Performance Audit

The Pharmaceutical Industry Investment Program—Assessment of Applicants

Department of Industry, Science and Resources

Australian National Audit Office

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Australian National
Audit Office

Canberra ACT
24 May 1999

Dear Madam President
Dear Mr Speaker

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

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

Yours sincerely

P. J. Barrett
Auditor-General

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

AUDITING FOR AUSTRALIA

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Contents

Abbreviations/Glossary

ANAO	Australian National Audit Office
DHAC	Department of Health and Aged Care (formerly the Department of Health and Family Services)
DIST	Department of Industry, Science and Tourism (now ISR)
ISR	Department of Industry, Science and Resources (formerly DIST)
OTC	Over-the-counter
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PIIP	Pharmaceutical Industry Investment Program
PVA	Production Value Added
R&D	Research and Development

Definitions

Broad Activities

Activities which are of strategic importance to the company and of benefit to Australia, including those which contribute to PVA and/or R&D activity targets[1].

European Union average price

The average European Union price determined from the ex-manufacturer prices of the same product (with adjustments made for differing dosages and pack sizes, if necessary) in a range of countries.

Six of the following countries should be used to calculate an European Union average price:

Austria	Belgium	Sweden
France	Germany	Ireland
Italy	Netherlands	Spain

United Kingdom[2].

Production Value Added

The difference between the ex-factory selling price of pharmaceutical products and the cost of ingredients, materials, royalties and other similar payments. Value added can also include income from royalties and other similar payments[3].

Research and Development

Systematic investigation or experimentation activities

- that involve innovation, technology transfer into Australia or technical risk;
- that are carried out in Australia;
- the object of which is new knowledge, or new or improved materials, products, processes, services or devices associated with the delivery of pharmaceutical products; and
- which have a direct link to or are of direct relevance to the pharmaceutical industry which can be demonstrated to the satisfaction of the Assessment/Administering Body[4].

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1 Department of Industry, Science and Tourism, April 1998, PIIP Program Guidelines, DIST, Canberra, p.3

2 Ibid p.7

3 Ibid p.4

4 Ibid, p.5

Summary

Audit Summary

Background

1. The Pharmaceutical Industry Investment Program (PIIP) will compensate the pharmaceutical industry, in part, for the impact of the Government exercising its monopsony power under the Pharmaceutical Benefits Scheme (PBS). The compensation takes the form of payment of higher prices on nominated products supplied by participating companies through the PBS, in return for those companies meeting commitments to undertake certain activities in Australia. PIIP commences on 1 July 1999 and replaces a similar program, the Factor f scheme, which ceases on 30 June 1999.

2. An Industry Commission report of May 1996 recommended reforms to the PBS[5]. The report also recommended that, if reform of the PBS is not an immediate priority, a revised Factor f scheme could be introduced in the interim. In April 1997, in response to the Industry Commission report, the Government announced that a revised scheme, to be known as the Pharmaceutical Industry Investment Program (PIIP), would be introduced on 1 July 1999 to run to 30 June 2004.

3. The Government allocated $300 million over five years to the Program to fund price increases and to cover administration costs. It was announced that entry to the Program would be competitive, based on the relative merits of the commitments set out in company applications for entry. The maximum total entitlement for any one company over the life of the Program was capped at $60 million.

4. During 1997 and 1998 the then Department of Industry, Science and Tourism consulted extensively with the pharmaceutical industry on the form the revised scheme was to take. Following this consultation the then Minister for Industry, Science and Tourism approved Program Guidelines. The Department then issued Application and Assessment Guidelines to industry in April 1998 and invited applications to participate in the Program. Applications closed on 21 August 1998 with 22 companies applying to participate. Two companies later decided to withdraw, following decisions by their parent companies, for reasons not connected to the assessment process.

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[5] Industry Commission May 1996, Report No. 51 : The Pharmaceutical Industry, AGPS, Canberra

5. The then Minister for Industry, Science and Tourism, in consultation with the then Minister for Health and Family Services, established an Assessment Panel of seven experts with wide-ranging knowledge of the pharmaceutical industry. The Panel was established to advise the Minister for Industry Science and Resources on the relative merits of applications and recommend which applicants should receive PIIP funding.

6. Panel members were selected on the basis of their knowledge and experience of pharmaceutical R&D, manufacturing and commercial operations, and the PBS. The Panel was supported by a Support Team within the Department of Industry, Science and Resources (ISR), which analysed the applications and provided that analysis, together with other information, to the Panel.

7. The Panel analysed the applications in detail and ranked them in order of relative merit, in relation to the PIIP principles as set out in the Program Guidelines. The Panel then recommended to the Minister which applicants should participate in the Program and the amount of the funds to be made available to each over the five years of the Program.

8. The Minister accepted the recommendations and announced the list of successful applicants on 11 December 1998[6]. These were: AMRAD Corporation Ltd, Astra Pharmaceuticals Pty Ltd, Bristol Myers Squibb Pharmaceuticals Pty Ltd, CSL, Eli Lilly Australia Pty Ltd, FH Faulding & Co Ltd, Janssen-Cilag Pty Ltd, Pfizer Pty Ltd, Pharmacia & Upjohn Pty Ltd and Glaxo Wellcome Australia Pty Ltd.

Audit objective and criteria

9. ISR sought the services of the Australian National Audit Office (ANAO) to provide ISR with an opinion on the probity of the methodology and procedures applied in the assessment process.

10. The objectives of the audit were to assist ISR in the timely identification of deficiencies in assessing responses from applicants and options for addressing any such deficiencies. This included:

- testing for adherence to principles of fairness and equity; and
- providing a report to the Parliament, the Government and other interested parties on the probity of the assessment process.

11. The ANAO provided advice, both orally and in writing, to ISR during the course of the audit.

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[6] Minister for Industry, Science and Resources Press Release 98/049, 11 December 1998. http://www.dist.gov.au/media/1998/december/dec98_20.html

12. The audit team was not involved in an executive role in managing the assessment process, but was available to provide advice where sought or where the ANAO perceived deficiencies or was aware of potential conflicts of interest. The audit was directed to the processes employed by ISR and the Assessment Panel to rank applicants according to merit, consistent with published PIIP Guidelines, and not to the technical assessments pertaining to the merits of the Programs offered by applicants; the perceived cost effectiveness of the PIIP Program; or whether the Department's administrative processes were efficient.

13. As part of the audit, suitable criteria were devised to enable the ANAO to assess the methodology and procedures developed by ISR, and to assist the ANAO to determine whether the assessment team adhered to those procedures. The ANAO also considered whether the process was conducted ethically and fairly and, in particular, whether there was the potential for bias and/or conflict of interest. In developing the criteria, the ANAO drew on the experience of earlier relevant audits.

Audit conclusion

14. The ANAO considers that the management structure ISR put in place was appropriate to the process and that:

a) the assessment process was free of bias and conflict of interest, as well as following closely the published guidelines;

b) the Assessment Panel had appropriate expertise and experience;

c) ISR and the Assessment Panel treated applicants for participation in the PIIP ethically, equitably and fairly in the assessment process; applicants were provided with timely advice; and the assessment process was completed within the published timeframe; and

d) ISR and the Assessment Panel took appropriate steps to maintain the confidentiality of commercial-in-confidence information, and maintained appropriate documentation, including records of decisions taken.

15. The ANAO concluded that ISR sought to address potential issues with respect to the PIIP Guidelines through consultation with industry and by publishing draft guidelines for comment. However, additional issues were raised by industry after the publication of the Application Guidelines. When this happened, ISR took appropriate steps to ensure that all potential applicants were advised of any changes and clarifications to the Guidelines.

16. The ANAO advised ISR that, to maintain adequate security for the Support Team, they should be located in a secure environment. The

Support Team was subsequently moved to a secure location. However, at times during the assessment process, other ISR staff were located in the same secure area. The latter staff were relocated following further advice from the ANAO. The collocation of ISR officers with the Support Team had the potential to breach the confidentiality of the process. The ANAO considers the security arrangements for information held on computers were appropriate.

17. In assessing eligibility, ISR and the Assessment Panel found it necessary to seek additional information from applicants. The ANAO considers the additional information was sought in a manner which was fair and equitable to applicants and reflected the aims and intention of the PIIP.

18. The ANAO provided advice during the course of the assessment, where it considered there were potential deficiencies in the process. ISR and the Assessment Panel responded appropriately to that advice.

Departmental response

19. DISR found the audit assistance and guidance throughout the process to be very helpful and considered that the audit strengthened the process and contributed to the positive results.

Audit Conclusions

1. Introduction

Background to PIIP

What is PIIP?

1.1 The Pharmaceutical Industry Investment Program (PIIP) will compensate the pharmaceutical industry, in part, for the impact of the Government exercising its monopsony power under the Pharmaceutical Benefits Scheme (PBS). The compensation takes the form of payment of higher prices on nominated products supplied by participating companies through the PBS, in return for those companies meeting commitments to undertake certain activities in Australia. PIIP commences on 1 July 1999 and replaces a similar program, the Factor f scheme, which ceases on 30 June 1999.

The pharmaceutical industry

1.2 In 1997–98 the pharmaceutical industry in Australia comprised over 120 companies; the value of production was $3.9 billion; exports were $1.1 billion; and the industry employed around 12 000 people. That year the cost of the PBS was $2.785 billion.

The Factor f scheme

1.3 The Factor f scheme has granted notional price increases for PBS products in return for increased activities conducted in Australia (see Appendix 1). The Department of Industry, Science and Resources (ISR) advised the ANAO that, under the Factor f scheme, industry had, by June 1998, achieved:

- a cumulative increase of $3.9 billion of Production Value Added (PVA) (see Figure 1);
- a cumulative increase of $572 million of Research and Development (R&D) expenditure (See Figure 1); and
- over 1000 new jobs.

1.4 The total of Factor f funding from 1988 to 1999 is expected to be around $1.1 billion.

Figure 1

Definitions

Broad Activities

Activities which are of strategic importance to the company and of benefit to Australia, including those which contribute to PVA and/or R&D activity targets[7].

Production Value Added (PVA)

The difference between the ex-factory selling price of pharmaceutical products and the cost of ingredients, materials, royalties and other similar payments. Value added can also include income from royalties and other similar payments[8].

Research and Development (R&D)

Systematic investigation or experimentation activities

- that involve innovation, technology transfer into Australia or technical risk;
- that are carried out in Australia;
- the object of which is new knowledge, or new or improved materials, products, processes, services or devices associated with the delivery of pharmaceutical products; and
- which have a direct link to or are of direct relevance to the pharmaceutical industry which can be demonstrated to the satisfaction of the Assessment/Administering Body[9].

Development and Implementation of PIIP

1.5 An Industry Commission report of May 1996 recommended reforms to the PBS[10]. The report also recommended that, if reform of the PBS is not an immediate priority, a revised Factor f scheme could be introduced in the interim. In April 1997, in response to the Industry Commission report, the Government announced that a revised scheme, to be known as the Pharmaceutical Industry Investment Program (PIIP), would be introduced on 1 July 1999 to run to 30 June 2004.

1.6 The Government allocated $300 million over five years to the Program to fund price increases and to cover administration costs (which are currently estimated to be of the order of $2.5 million). It was announced that entry to the Program would be competitive, based on the relative merits of the commitments set out in company applications for entry. The maximum total entitlement for any one company over the life of the Program was capped at $60 million. The Program commitments comprise two elements:

- PVA and/or R&D activity targets—commitments to achieve PVA and/or R&D targets which incorporate both existing and additional activity; and

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7 Department of Industry, Science and Tourism April 1998, PIIP Program Guidelines, DIST, Canberra, p 3

8 Ibid p 4

9 Ibid, p 5

10 Industry Commission May 1996, Report No. 51 : The Pharmaceutical Industry, AGPS, Canberra

- Broad Activity Commitments—commitments to undertake broad activities which are of strategic importance to the company and of benefit to Australia, including those which contribute to PVA and/or R&D activity targets.

1.7 During 1997 and 1998 the then Department of Industry, Science and Tourism consulted extensively with the pharmaceutical industry on the form the revised scheme was to take. Following this consultation the then Minister for Industry, Science and Tourism approved Program Guidelines. The Department then issued the Program Guidelines and associated Application and Assessment Guidelines to industry in April 1998 and invited applications to participate in the Program.

1.8 The Program operates according to four guiding principles, which outline the objectives of PIIP and which were set out in the Program Guidelines. These principles are listed in Figure 2.

Figure 2

Pharmaceutical Industry Investment Program Principles

Principle 1

The Pharmaceutical Industry Investment Program is intended to increase the total level of research and development activity undertaken in Australia which has a direct link to or is of direct relevance to the pharmaceutical industry. It is not, however, intended to influence the direction of that research and development activity.

Principle 2

The Pharmaceutical Industry Investment Program is intended to increase the total level of pharmaceutical production value added activity undertaken in Australia. In particular, it seeks to encourage high value adding per unit activity over lower value adding per unit activity.

Principle 3

The Pharmaceutical Industry Investment Program is intended to encourage pharmaceutical companies to achieve not only growth in existing activity but also to undertake additional activity which is different in scope from existing activity, or is otherwise new to the company and of 'significance' to its operations and/or its position in the global environment.

Principle 4

The Pharmaceutical Industry Investment Program is intended to encourage a sustainable pharmaceutical industry in Australia, undertaking activity which is internationally competitive and of benefit to Australia.

1.9 The Applications Guidelines advised applicants that, to participate in PIIP, a company must:

- be a company incorporated under Australian Corporations Law;
- demonstrate that products the company supplied under the PBS are price suppressed, according to the European Union average price, due to the government exercising its monopsony purchasing power under the PBS; and

- propose activities that are eligible according to the principles stated in the PIIP Guidelines.

1.10 Applications closed on 21 August 1998 with 22 companies applying to participate. Two companies later decided to withdraw, following decisions by their parent companies, for reasons not connected to the assessment process.

1.11 The then Minister for Industry, Science and Tourism, in consultation with the then Minister for Health and Family Services, established an Assessment Panel of seven experts with wide ranging knowledge of the pharmaceutical industry. The Panel was established to advise the Minister for Industry Science and Resources on the relative merits of applications and recommend which applicants should receive PIIP funding.

1.12 Panel members were selected on the basis of their knowledge and experience of pharmaceutical R&D, manufacturing and commercial operations, and the PBS. The Panel was supported by a Support Team within ISR, which analysed the applications and provided that analysis, together with other information, to the Panel.

1.13 The Panel analysed the applications in detail and ranked them in order of relative merit in relation to the PIIP principles as set out in the Program Guidelines. The Panel then recommended to the Minister which applicants should participate in the Program and the amount of the funds to be made available to each applicant over the five years of the Program.

1.14 The potential amount of funding for each applicant was determined by the activities offered in their application, and agreement by the Assessment Panel that the activities were eligible for funding. As the funding made available by the Government was less than the total applied for by all applicants, funds were allocated to applicants in order of ranking until the available funds were exhausted. It was therefore important that the Assessment Panel give particular attention to applicants that were close to the cut-off point for funding, where the precise ranking could determine whether the applicant received funds.

1.15 The Minister accepted the recommendations of the Assessment Panel and announced the list of successful applicants on 11 December 1998[11]. Table 1 shows the successful applicants and the level of PIIP funding allocated to each over the five years commencing 1999.

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[11] Minister for Industry, Science and Resources Press Release 98/049, 11 December 1998. http://www.dist.gov.au/media/1998/december/dec98_20.html

Table 1
Listing of successful applicants and allocated funds

Company	*PIIP Funding ($)*
AMRAD Corporation Ltd	24 584 979
Astra Pharmaceuticals Pty Ltd	6 036 047
Bristol Myers Squibb Pharmaceuticals Pty Ltd	39 382 550
CSL	60 000 000
Eli Lilly Australia Pty Ltd	19 883 000
FH Faulding & Co Ltd	40 845 027
Janssen-Cilag Pty Ltd	17 502 918
Pfizer Pty Ltd	52 500 000
Pharmacia & Upjohn Pty Ltd	33 904 847
Glaxo Wellcome Australia Pty Ltd	see note

Note: Glaxo Wellcome received an offer of funding during the first round—the exact amount to be allocated to the company will be determined after the contracts with the other successful companies have been concluded.

1.16 As indicated previously, the Government allocated a total of $300 million over five years to fund the program.

Operation of PIIP

1.17 Participants in PIIP will be paid quarterly, in arrears, on receipt of a statement of activity undertaken in the quarter. The maximum annual entitlement for participants is determined by the activities offered in their applications for each year of the five-year program. Over-performance in a year (ie. activities that would generate entitlements in excess of those offered) can be carried over to following years, and in some circumstances, under-performance can be offset against over-performance. There will be an annual assessment of participants' performance against all program commitments; the final quarterly payment for each year will not be made until this assessment is completed. The data provided for this assessment is required to be audited by an auditor retained by the participant.

1.18 The PIIP Guidelines provide for further entry of companies in the event that the allocated funds are not fully utilised. This situation may arise if participating companies are unable to comply with their commitments.

1.19 The PIIP Guidelines state that, in the interests of accountability and transparency in the use of taxpayers funds, information about the operation and outcomes of the PIIP will be made available to the public through an annual report to Parliament

Reason for the audit

1.20 ISR sought the services of the ANAO to provide ISR with an opinion on the probity of the methodology and procedures applied in the assessment process while the latter was in progress. The ANAO undertook to provide ongoing oral advice on probity issues as the occasion demanded and to confirm that advice by letter. In undertaking the audit, the ANAO notified ISR that it intended to report the results to Parliament.

1.21 The ANAO commenced the audit in August 1998, two days before applications for participation in the scheme closed.

Audit objective and scope

1.22 The objectives of the audit were to assist ISR in the timely identification of deficiencies in assessing responses from applicants and options for addressing any such deficiencies. This included:

- testing for adherence to principles of fairness and equity; and
- providing a report to the Parliament, the Government and other interested parties on the probity of the assessment process.

1.23 The ANAO provided advice, both orally and in writing, to ISR during the course of the audit.

1.24 The audit team was not involved in an executive role in managing the assessment process, but was available to provide advice where sought or where the ANAO perceived deficiencies or was aware of potential conflicts of interest. The audit was directed to the processes employed by ISR and the Assessment Panel to rank applicants according to merit, consistent with published PIIP Guidelines, and not to the technical assessments pertaining to the merits of the programs offered by applicants; the perceived cost effectiveness of the PIIP Program; nor to the efficiency of the Department's administrative processes.

Audit criteria and methodology

1.25 As part of the audit, suitable criteria were devised to enable the ANAO to assess the methodology and procedures developed by ISR, and to assist the ANAO to determine whether the assessment team adhered to those procedures. The ANAO also considered whether the process was conducted ethically and fairly and, in particular, whether there was the potential for bias and/or conflict of interest. In developing the criteria, the ANAO drew on the experience of earlier relevant audits.

1.26 The audit criteria were as follows:

- the assessment process adopted by ISR was free from bias and potential conflicts of interest;
- applicants were treated ethically, equitably and fairly in the process;
- the confidentiality of commercial-in-confidence material supplied to ISR was maintained;
- the assessment methodology, as published in the PIIP Guidelines, was followed and any departures from the methodology appropriately notified to applicants;
- appropriate records were maintained; and
- decisions were adequately supported and documented.

1.27 In conducting the audit the ANAO:

- examined related files and records held by ISR;
- examined the assessment methodology and procedures;
- observed meetings between applicants, the Assessment Panel and the ISR Assessment Panel Support Team;
- considered the transparency and fairness of the process; and
- examined the final report on the assessment.

1.28 During the course of the audit the ANAO, as an observer, attended meetings of the ISR PIIP Management Committee. Oral reports on matters which the ANAO considered required attention were given to ISR and later confirmed in writing.

1.29 The audit was conducted as an audit by arrangement under section 20 of the *Auditor-General Act 1997*. The audit conformed with ANAO Auditing Standards and cost $75 535, of which $28 201 was recovered in fees from ISR.

2. Management of the Assessment Process

This chapter provides a brief description of the management of the process and provides an audit opinion of the management structure.

Overall audit opinion

2.1 The ANAO considers that the management structure ISR put in place was appropriate to the process and that:

a) the assessment process was free of bias and conflict of interest, as well as following closely the published guidelines;

b) the Assessment Panel had appropriate expertise and experience;

c) ISR and the Assessment Panel treated applicants for participation in the PIIP ethically, equitably and fairly in the assessment process; applicants were provided with timely advice; and the assessment process was completed within the published timeframe; and

d) ISR and the Assessment Panel took appropriate steps to maintain the confidentiality of commercial-in-confidence information, and maintained appropriate documentation, including records of decisions taken.

2.2 The ANAO concluded that ISR sought to address potential issues with respect to the PIIP Guidelines through consulting with industry and by the publishing draft guidelines for comment. However, industry raised additional issues after the publication of the Application Guidelines. When this happened, ISR took appropriate steps to ensure that all potential applicants were advised of any changes and clarifications to the Guidelines.

2.3 The ANAO advised ISR that, to maintain adequate security for the Support Team, they should be located in a secure environment. The Support Team was subsequently moved to a secure location. However, at times during the assessment process, other ISR staff were located in the same secure area. The latter staff were relocated following further advice from the ANAO. The collocation of ISR officers with the Support Team had the potential to breach the confidentiality of the process. The ANAO considers the security arrangements for information held on computers were appropriate.

2.4 In assessing eligibility, ISR and the Assessment Panel found it necessary to seek additional information from applicants. The ANAO considers the additional information was sought in a manner which was

fair and equitable to applicants and reflected the aims and intention of the PIIP.

2.5 The ANAO provided advice during the course of the assessment, where it considered there were potential deficiencies in the process. ISR and the Assessment Panel responded appropriately to that advice.

Timetable

2.6 The Department completed the assessment process within the original timetable as notified to applicants, and is on target to meet the Government's date for commencement of the Program on 1 July 1999. Figure 3 lists the key events together with the actual and, where applicable, the target date for the event.

Figure 3

Key events

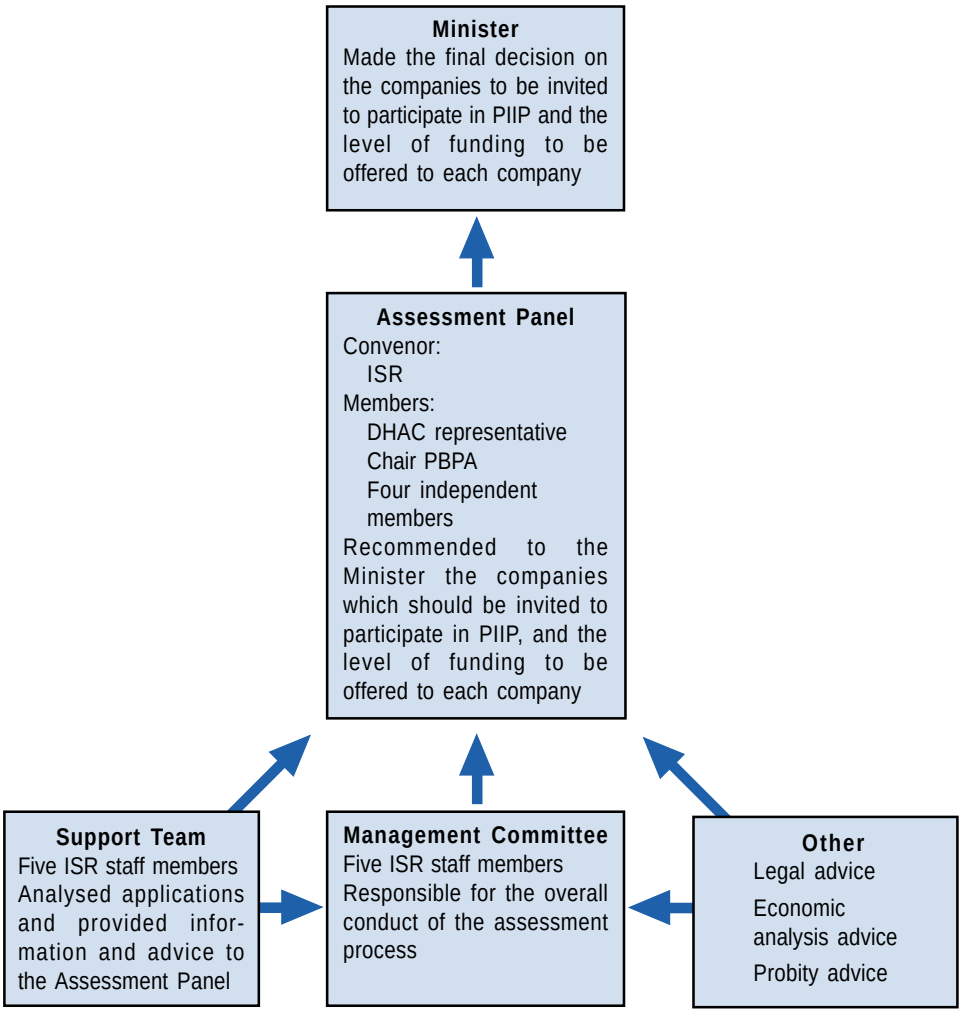
Event	*Target Date*	*Actual Date*
Government announcement of PIIP		April 1997
Consultations with industry		April 1997–April 1998
Release of PIIP Guidelines		April 1998
PIIP Seminars		May 1998
Notification of intention to make an application (not obligatory)	29 May 1998	29 May 1998
Additional information paper #1		23 June 1998
Additional information paper #2		9 July 1998
Additional information paper #3		29 July 1998
Additional information paper #4		10 August 1998
Advice re treatment of pharmaceutical ingredient as eligible PVA		12 August 1998
Extension of closing time by one week		13 August 1998
ANAO commenced audit		19 August 1998
Additional information paper #5		20 August 1998
Consolidation of additional papers		21 August 1998
Close of applications	14 August 1998	21 August 1998
Minister approves Assessment Panel membership		28 August 1998
Initial Assessment Panel meeting		14 September 1998
Additional information sought on quantitative data		2 October 1998
Assessment Panel Meeting		16 October 1998
Additional information sought on PVA activity		21 October 1998
Applicant presentations to the Assessment Panel		26–29 October 1998
Assessment Panel meeting		5 November 1998
Assessment Panel final recommendations		12–13 November 1998
Minister's announcement of successful applicants	End 1998	11 December 1998
PIIP Commences	1 July 1999	
PIIP Concludes	30 June 2004	

Management structure

2.7 At the time of commencing the audit, the related management structure was still emerging. The ANAO provided advice on the structure. In particular the ANAO advised of the need to formalise the role of the ISR officers providing policy advice and administrative support. This was achieved by forming a Management Committee. The administrative structure for managing the process of assessing the applications and for providing support to the Assessment Panel is shown in Figure 4.

Figure 4

Established Management Structure



Assessment Panel

2.8 The role of the Panel was to determine the eligibility of activities proposed by PIIP applicants; assess the merits of each application; and rank the applications on the basis of relative merit. The Panel then

recommended to the Minister for Industry, Science and Resources which applicants should be invited to participate in the PIIP, and the funds for which the applicant was eligible.

2.9 On the basis of these recommendations, the Minister decided which applicants were offered entry to the Program and the level of funding available to each applicant. Assessment Panel members are listed at Appendix 2 and the Terms of Reference of the Panel are at Appendix 3.

Assessment Support Team

2.10 The Panel was supported by a team of ISR officers (the "Support Team"). The Support Team responsibilities included:

- checking that each applicant was a company incorporated under Australian Corporations Law and, where there was a group of companies that were related bodies corporate, only one of those companies made a PIIP application;
- ensuring that applicants could apply the price increases against eligible products; and
- verifying that the proposed activity (R&D, PVA) satisfied the eligibility requirements outlined in the PIIP Guidelines.

2.11 The team members also produced summaries of the applicants in standard format for the Assessment Panel and were able to provide information to the Panel on details of the application, when the Panel sought such information.

2.12 The Support Team also kept the documentation of the process, including minuting meetings and recording decisions taken by the Panel and the Management Committee.

Management Committee

2.13 The Management Committee comprised ISR officers and was responsible for:

- the overall conduct of the assessment process;
- providing policy and operational directives to the Assessment Support Team;
- approving the assessment procedures and methodology, consistent with the published PIIP Guidelines, with the authority to alter them if necessary;
- all contacts with the applicants; and
- administrative and operational matters relating to the assessment process.

Appendix 4 gives the full Terms of Reference of the Committee.

Other advice

2.14 During the course of the assessment process, ISR and the Assessment Panel sought legal advice on a number of occasions, from both the Attorney-General's Department and the private sector. Probity advice was provided by the ANAO and the legal advisers.

2.15 ISR and the Assessment Panel gathered additional quantitative data from applicants after the close of applications. The data were to assist in the assessment of net benefits of proposals on a range of economic and financial indicators. These quantitative data were analysed by a Branch of ISR specialising in economic analyses and the results of the analysis were provided to the Assessment Panel.

Conclusion

2.16 The ANAO considers that the management structure was appropriate to the process.

Conflict of interest

2.17 The ANAO expects that, in any process of the nature of the PIIP assessment process, the agency managing the process will seek a declaration from all those involved in the process of any actual, potential or perceived conflict of interest and deal appropriately with any real or potential conflicts of interest that this reveals.

2.18 ISR sought a declaration of conflict of interest from all people involved in the assessment process. There were no current conflicts of interest declared. ISR was aware that some Assessment Panel members had previous affiliations or employment with applicant companies. This was dealt with by publishing the information on the ISR Internet site when announcing the members of the Panel.

2.19 The ANAO considers that ISR took appropriate steps to determine if any person involved in the assessment had any potential conflict of interest. The ANAO also considers the declaration of previous affiliations of Panel members was appropriate.

PIIP Guidelines

Development of Guidelines and additional information

2.20 ISR consulted extensively with the pharmaceutical industry in developing the Program Guidelines and the Application and Assessment Guidelines for the PIIP. This included seeking comment on draft versions of the Guidelines. Following those consultations, the then Minister for Industry Science and Tourism approved Program Guidelines which were published in April 1998. At the same time ISR published information and

guidance for companies in preparing their applications and outlined the assessment process (PIIP Application and Assessment Guidelines). However, following publication of the Guidelines, companies raised further issues. This occurred both during public seminars on the PIIP and, particularly, in meetings between ISR staff and individual companies which were held to clarify issues relating to PIIP applications. ISR addressed issues raised in this way in a series of Additional Information Papers which were sent to all companies which had indicated their intention to apply for the PIIP. As well as being provided to all interested parties, these papers were provided on the ISR Internet site and later published in a consolidated form as the Supplementary Guidelines. This approach was adopted to ensure that all potential applicants were treated equitably and were fully informed of the parameters of the PIIP.

2.21 The issues addressed in the first four Additional Information Papers, issued between 23 June and 10 August 1998, took three forms. Firstly, some issues were largely a matter of clarification. That is, they addressed issues which were covered in the Guidelines but which subsequent discussions with industry had indicated needed to be explained more fully if they were to be clearly and consistently understood by all potential applicants.

2.22 A second group of issues discussed in these Papers were issues which had not been addressed in the published Guidelines. These were generally issues of detail which came to the attention of companies when they sought to apply the PIIP Guidelines to their particular circumstances in formulating applications. For example, a number of companies sought guidance on how to treat, in their applications, a 'negative entitlement'. That is, a circumstance in which the value of either PVA or R&D activity in any given year was lower than in the base year. In determining total entitlements over the life of the program, applicants were unsure whether to accord a zero or a negative entitlement value in such a circumstance. It was considered necessary to provide guidance to applicants that, in these circumstances, a negative entitlement value should be used in the application.

2.23 The third set of issues discussed in the first four Additional Information Papers were revisions to the published Guidelines necessary to maintain the integrity of the assessment process and / or administration of the Program. These revisions were made necessary as a consequence of companies providing new information to ISR. For example, the original Application and Assessment Guidelines requested that applicants provide annual unit sales data for all products included in their PVA activity targets. However, several companies informed ISR that the provision of

such data, on a meaningful basis, would result in many hundreds of product entries. It was therefore decided to delete the requirement as it would have made the assessment process extremely cumbersome.

2.24 A fifth Additional Information Paper outlined further information on the PIIP Assessment Panel and the body to administer the Program. As such, it did not actually provide new information relevant to the completion of applications. It would therefore have been preferable for ISR to have labelled this as a contextual or background paper, for example, so as to avoid any misunderstanding that new information was being provided at late notice.

2.25 The ANAO concluded that ISR sought to address potential issues with respect to the PIIP Guidelines through consulting with industry and by publishing draft guidelines for comment. However, industry raised additional issues after publication of the Application Guidelines. When this happened, ISR took appropriate steps to ensure that all potential applicants were advised of any changes and clarifications to the Guidelines.

2.26 The ANAO considers that ISR took appropriate steps to ensure all applicants were advised of changes and clarifications to the Guidelines.

Change of closing date

2.27 The ANAO noted that, late in the application period, company queries revealed an inconsistent understanding on the eligibility of third party pharmaceutical ingredient manufacture to be included as eligible PVA. ISR wrote to potential applicants on 12 August clarifying the relevant definition. On 13 August 1998 ISR wrote to potential applicants advising that, because the late clarification of this issue left little time for prospective applicants to assess their circumstances, the application period would be extended by one week to 21 August 1998. The letter also advised prospective applicants that arrangements will be in place to accept applications from 14 August (the original closing date) and that any applications already submitted could be withdrawn and resubmitted by the new closing date.

2.28 Following this late change some applicants:

- submitted their documents by the new closing date;
- revised their application, in one instance the application was at the printers was withdrawn and reprinted; or
- submitted their documents on the original closing date of 14 August 1998.

2.29 The ANAO commenced its audit of the process on 19 August 1998 and was therefore unable to provide concurrent advice to ISR on the above issue. On commencing the audit, the ANAO advised ISR of its view that the late revisions or clarifications to the original Guidelines were undesirable. However, in this instance, where a misunderstanding of the Guidelines became evident late in the application period, ISR actions were appropriate. These actions included extending the closing date for applications, and ensuring potential applicants were given an equal opportunity to revise their applications.

Receipt of applications

2.30 The ANAO considers that applications should not be opened until after the closing of applications to ensure that no advantages accrue to applications opened and examined early, and to demonstrate that confidentiality of applicants is maintained until all applications have been lodged. ISR opened and registered those applications that were lodged early (some applications were delivered unpackaged) and then held the applications in secure storage. The ANAO commenced the audit two days before the close of applications on 21 August 1998 and immediately advised that, in the ANAO's view, applications should not be opened until after the closing time for applications to reduce the risk of unauthorised disclosure of the confidential information contained in the applications. ISR followed the ANAO advice for those applications lodged after the advice was provided. Applications were not examined or considered before the closing date.

Assessment procedures and the assessment process

2.31 The expectation of the ANAO was that, consistent with good practice, the procedures and methodology for the assessment process would be finalised before the closure of receipt of applications. The procedures and methodology included the administrative and operational arrangements for the process as well as the detail of how the comparative assessment of applications was to be undertaken. In the event, at the close of applications on 21 August 1998, the procedures and methodology were still under development.

2.32 Finalisation of the procedures and methodology was complicated by the need for the comparative assessment methodology to be agreed by the Assessment Panel. The Minister established the Panel on 28 August 1998 and it first met on 14 September. At that meeting, ISR provided the Assessment Panel with a proposed methodology for assessing and ranking applications. The Panel commented on and agreed to the methodology

out of session. Copies of company applications were not distributed to the Panel until they had agreed on the assessment methodology and received advice on probity issues. The final version of the methodology and procedures was provided to the Panel at its second meeting on 16 October. In developing the final version, ISR and the Panel took into account the advice provided by the ANAO on probity matters.

Additional information requested from industry

2.33 The assessment was carried out in three stages. These stages were:

- determining the eligibility of companies to be considered for participation in PIIP;
- assessing the merit of the applications against the four PIIP principles; and
- a comparative assessment of the applications and a determination of the order of merit of applicants.

2.34 In undertaking the first stage—determining the eligibility of applicants to participate—ISR and the Assessment Panel found that it was necessary to seek additional information from applicants. The additional information sought fell into the following three categories:

a) additional information from all applicants which was not asked for in the initial PIIP Guidelines;

b) additional information from all applicants which sought PVA funding, clarifying their PVA base; and

c) specific information from individual applicants clarifying their application.

2.35 The additional information was sought and obtained between the closing of applications and the Assessment Panel making a final determination on its recommendations to the Minister. In all cases, applicants were advised that the information sought was to clarify information provided in the original application and that new or additional arguments in support of their application would not be considered.

a) Additional information not originally sought

2.36 After an initial examination of the applications, ISR concluded that additional quantitative data would assist in assessing the net benefits of each application. The Assessment Panel, at its first meeting, agreed that such a quantitative analysis would be beneficial in providing a mechanism to assist the ranking of applications and asked ISR to obtain

the necessary information. The information sought included company expenditure, with and without PIIP, on employment, production and investment. The expenditure was sought for the period from 1996–97 to 2003–04.

2.37 ISR also sought legal advice on a draft letter and questionnaire which would be sent to applicants to obtain these data. The legal advice was that the information being sought could be seen to be treating PVA and R&D applications differentially. ISR therefore revised the information being sought to present PVA and R&D applications as being treated equally, that is PVA would be compared with other applicants' PVA, and R&D compared with other applicants' R&D. PVA would not be compared with R&D. ISR did not seek legal advice on the revised letter and questionnaire.

2.38 The ANAO considers that it was reasonable for ISR and the Assessment Panel to request the additional information. Whilst the ANAO has no reason to consider any applicant was disadvantaged by the revised request, it would have been prudent for ISR to have requested legal advice on the revised letter and questionnaire.

b) Clarification of the PVA base

2.39 The PVA guidelines specifically state that applicants

> *must encompass all eligible PVA activity proposed to be undertaken by the company during the PIIP—companies cannot restrict the PVA activity proposed in their applications to a subset of their eligible activity.*

Although the ANAO did not audit this part of the process, ISR advised the ANAO that the requirement had been emphasised at meetings with the pharmaceutical industry leading up to receipt of applications. During examination of the applications it appeared that some applicants had not included all their eligible PVA activity. This view was based on the ISR officers' knowledge of the pharmaceutical industry.

2.40 The risk to the assessment process of some applications not including all eligible PVA activity was that an applicant had the potential to appear to have submitted a better application than would otherwise have been the case. Hence the applicant may be ranked higher than others which had detailed all their eligible PVA activity, with the possibility of disadvantaging the latter.

2.41 Dealing with this issue presented a challenge for ISR and the Assessment Panel in that there was potential for inequitable treatment of some applicants. ISR and the Panel sought legal advice on the issue and the ANAO provided comments. The course of action taken by ISR and the Assessment Panel was to write to all applicants who were seeking

funding for their PVA activity, asking them to review their eligible PVA activity. The letter advised that, where the revised information resulted in a lower entitlement to PIIP funding, the lower figure would be used, and, where the revised information resulted in a higher entitlement, the original entitlement would be used.

2.42 Other possible actions that could have been taken instead were:

- eliminating those applicants judged to have not included all their eligible PVA; or
- accepting the eligible PVA activity as stated in the original application.

2.43 The first possible action had the potential to eliminate the bulk of the applicants, including some which were otherwise of good quality and which met the aims and intentions of PIIP. The second action had the potential to place applicants with inaccurate information ahead of applicants who provided full and accurate PVA figures to the detriment of the latter.

2.44 Companies in receipt of PIIP funds will be required to provide audited data to ensure that they only receive funds to which they are eligible. Hence, any inaccurate information provided in applications will be audited, corrected, and the funding adjusted in due course. However, without accurate assessment information, there would be some risk to the Program's objectives in that the PIIP funds may not be fully spent, and that eligible companies would be eliminated. For these reasons, ISR and the Assessment Panel decided that the best course of action was to require all applicants to review their PVA figures and provide full and accurate information.

2.45 Following the letter, several applicants contacted ISR. ISR informed the applicants of discrepancies between the information provided in their application and the ISR understanding of the situation. The applicants wrote to ISR either submitting revised information or explaining the discrepancy. ISR concluded, after receiving revised information from the applicants, that the discrepancies were due to error and to applicants' misunderstanding of eligibility. ISR considered that there was no intention of any applicant to deliberately mislead the Assessment Panel.

2.46 The ANAO considers that, in the circumstances, asking applicants to review their eligible PVA activity, compared with the other possible courses of action stated above, was the fairest and most equitable to all applicants. It also reflected the aims and intention of the PIIP scheme more accurately than other options.

c) Individual information

2.47 In some instances individual applicants were asked to clarify their proposal. Matters requiring clarification included such issues as which products companies intended to seek to be listed on the PBS and the production arrangements between companies where one company contracts a second company to manufacture a product. ISR sought and followed legal advice on the general form of the letters.

2.48 The ANAO examined the letters and the process generally and found that the process of clarification was undertaken in an appropriate manner.

2.49 The ANAO considers that additional information was sought from applicants in a fair and open manner, and applicants were treated equitably.

Assessment Panel

2.50 The Assessment Panel membership was widely based. Members included representatives from academia with expertise in R&D, former executives of pharmaceutical companies with experience of the production of drugs, the chair of the Pharmaceutical Benefits Pricing Authority responsible for managing the Factor f scheme, a medical practitioner in his official capacity as the representative of the Department of Health and Aged Care, and public officials with understanding of the Government's requirements of the PIIP Program. Some members had expertise in several areas.

2.51 In establishing membership of the Assessment Panel the Minister for Industry, Science and Resources, together with the Minister for Health and Aged Care, agreed that the Department of Health and Aged Care (DHAC) would be represented on the Panel. DHAC has responsibility for the operation of the PBS. DHAC had some difficulty identifying a representative without the potential for a conflict of interest between this assessment process and the administrative requirements of the PBS scheme. The consequent delay in appointing the DHAC representative meant that that member was not appointed in sufficient time to attend the first two meetings of the Assessment Panel.

2.52 The ANAO considers that Assessment Panel members had appropriate expertise and the experience and background of the members covered areas to be addressed in assessing the applicants.

2.53 The Assessment Panel completed its task in logical stages, as follows:

- agreement on the methodology to be used to determine the merits of applicants and to compare applications;

- examination of applications and resolution of issues;
- applicant presentations in support of their case for participation in PIIP;
- agreement on the methodology for ranking applicants;
- each Panel member ranked each applicant out-of-session. The seven individual rankings were then combined to give a preliminary overall rank of applicants; and
- the Panel met to consider the comparative merit of each applicant in detail. The preliminary ranking was adjusted, where considered appropriate, to give a final ranking of applicants. While all applicants were discussed in detail in this Panel session, particular attention was paid to applicants that were close to the cut-off point for funding, where the precise ranking could determine whether the applicant received funds.

2.54 During the detailed examination of applicants the Assessment Panel, through the Support Team, documented the rationale behind their ranking of applicants. This rationale was available for the later debriefing of applicants on the merits of their application. In particular it was used for advising the unsuccessful applicants about their lack of success.

2.55 The ANAO observed all Assessment Panel meetings. The ANAO observed that all members were provided with an opportunity to put forward their views. The Panel paid particular attention to ensuring that all applicants were treated equally and fairly.

2.56 The ANAO considers that the Assessment Panel treated all applicants equally and fairly, and that the methodology adopted by the panel was likely to result in applicants being ranked in order of merit, according to the PIIP principles.

Company presentations

2.57 All applicants were invited to meet the Assessment Panel and present their company's case for inclusion in the PIIP. Although not mandatory, all applicants accepted the invitation. Presentations were held in Sydney and Melbourne.

2.58 All applicants were advised of the Assessment Panel's expectations. In particular they were advised of the time allowed for the presentation and for the Panel to ask questions of the applicant, and of the maximum number of applicant representatives who may be present. Applicants were also advised that there should be no new or additional argument, not included in the company's application, since such argument would not be taken into consideration in assessing the application.

2.59 The ANAO observed the presentations of all applicants. The ANAO noted that all applicants were allowed to present their case as they saw it; that all presentations held reasonably to the times allowed; and that the Panel's questions of the applicants were reasonable and fair both in terms of the content of questions and in the manner in which they were asked.

2.60 The ANAO considers that the Assessment Panel conducted the applicant presentations in a manner which was fair and equitable to all applicants.

Contact with industry

2.61 The assessment procedures developed by ISR (paragraph 2.31) restricted contact with PIIP applicants to people defined by the Management Committee. The defined people were the Manager of the PIIP Assessment Support Team and a member of the Management Committee. However, ISR also recognised that some ISR officers who were involved in the assessment process had contact with the pharmaceutical industry, including PIIP applicants, as part of their normal day-to-day operations. The ANAO advised ISR that the PIIP assessment process should not be discussed during such day-to-day contact.

2.62 The assessment procedures also required members of the PIIP Assessment Panel to refrain from direct contact with applicants and not to accept hospitality from applicants. The procedures required that members direct any applicants contacting them to the manager of the Support Team.

2.63 The ANAO considers that the assessment procedures dealt appropriately with contact with industry and, in the course of the ANAO's observation of the process, the ANAO was not aware of any breaches of the procedures.

Accommodation, security, computers

Accommodation

2.64 The PIIP Support Team was provided with accommodation within ISR. The accommodation was secured by a magnetic stripe card security lock. Documents were stored in C Class security cabinets and a clean desk policy employed. ISR reviewed people with access to the area at the start of the assessment and removed non-essential staff from the list of people with access.

2.65 The accommodation was initially shared with two ISR Senior Executives and their Personal Assistant. These ISR officials, who had no

connection with the PIIP assessment, were relocated after a short period. A further Senior Executive was located in the same area for a short period later in the process.

2.66 The ANAO recognised that the first instance of sharing the accommodation was for a limited time only, early in the assessment process, and was unlikely to result in a breach of confidentiality. However, noting the second occurrence, the ANAO advised of its concern that the accommodation was being shared and of the potential for a breach of the security of the process. ISR noted the ANAO's concern and relocated the ISR staff elsewhere, leaving the Support Team only in the secure area.

2.67 The ANAO considers that it would have been prudent for ISR to have ensured the early separate location of the Support Team.

Computer security

2.68 At the start of the assessment the ANAO advised ISR of the need to secure the computers used to store information about the assessment against unauthorised access. The ANAO also advised that disconnection from the ISR network would ensure security of the computers within the secure accommodation. This was because any connection to the ISR network would allow ISR staff with supervisor access authority to override any security arrangements. ISR noted the ANAO advice. However, ISR considered that, in view of potential problems of maintaining a stand alone network and of isolating the Support Team from the ISR email system, providing a secure directory for the Support Team was adequate for the assessment purpose. Access to the directory was limited to authorised Support Team personnel and ISR IT security staff.

2.69 The ANAO considers that the security of the information stored on the ISR computers was adequate for the assessment process.

Assessment Panel security

2.70 Assessment Panel members, as with all those involved in the assessment process, signed a document acknowledging the confidentiality of the information provided and agreeing not to disclose the information without the consent of the Chair of the PIIP Assessment Panel.

2.71 Members needed access to the company application documents at their places of work, or at home, to study the applications and assess their merit. This need posed particular problems of maintaining the confidentiality of the documents when in transit to members and when stored at members' homes or work.

2.72 In consultation with Panel members, ISR security staff assessed the risk and determined the secure storage needs of each member and, where necessary, supplied secure storage. Appropriate containers were also supplied to members for transporting documents, when transport was necessary.

2.73 The ANAO considers that ISR took appropriate steps to ensure that Assessment Panel members were aware of their security responsibilities, to provide members with secure storage and to provide secure transport for the application documents and papers related to the assessment process.

Timeliness

2.74 ISR completed the assessment process within the announced timeframe of the end of 1998. The announcement of successful applicants was made by the Minister on 11 December 1998.

Legal advice

2.75 ISR and the Assessment Panel appropriately sought legal advice on a number of issues. The ANAO noted that, on occasions, legal advice was sought and provided orally. The expectation of the ANAO is that legal advice should be sought and provided formally in writing for appropriate assurance to all concerned. Where oral advice is given, it is equally prudent that later written confirmation is also provided. Written questions determine the scope of the legal advice. Written responses ensure that there is no misunderstanding, if questions arise later in connection with the advice. The advice is also available for audit and other purposes. Without written advice there is often a doubt about exactly what was said, as recollections differ, especially after a lapse of time.

2.76 Following the ANAO's advice, ISR sought subsequent legal advice in writing.

Canberra ACT
24 May 1999

P. J. Barrett
Auditor-General

Appendices

Appendix 1

The Factor f scheme

The Factor f scheme[12] grants notional price increases for PBS products in return for increases in activities conducted in Australia. It is called 'Factor f' because factors to be taken into account in setting prices are identified alphabetically—industry activity is the sixth factor. The main features of the scheme are that:

- companies are eligible to enter the scheme if they meet and maintain increases in eligible activity (R&D and PVA), or otherwise prove they are making a significant contribution to internationally competitive production in Australia;
- payments are a maximum of 25 per cent of the value of additional activity over the level that existed in the base year (typically the year before the company entered the scheme);
- payments are translated into notional price increases for PBS products. The maximum price increase is to the level of the average European price of the product. The actual prices of products are not affected; and
- payments to companies are made quarterly in arrears.

The Factor f scheme commenced in 1988 and is due to conclude on 30 June 1999.

[12] Industry Commission May 1996, Report No. 51 : The Pharmaceutical Industry, AGPS, Canberra

Appendix 2

Assessment Panel

The seven members of the PIIP Assessment Panel were:

Mr Alan Evans, Panel Convenor, Department of Industry, Science and Resources

Professor John W Funder AO, Director of the Baker Medical Research Institute

Professor Merilyn Sleigh, Dean, Faculty of Life Sciences, University of New South Wales

Mr Michael Kimber, consultant/industrial pharmacist

Mr Robert Bowen, State Manager, AusIndustry Business Networks Program

Mr Graham Glenn, Chair, Pharmaceutical Benefits Pricing Authority

Dr Peter MacIsaac, Medical Adviser representing the Department of Health and Aged Care

The relevant experience of each member of the Panel is detailed below.

Mr Alan Evans

Mr Evans has been the Head of Division, Industry Division A, Department of Industry, Science and Resources for two years. This Division includes the pharmaceutical and health industries section. He has held a number of senior positions in both the public and private sectors, including Head of AusIndustry and of the Commonwealth Office of Regional Development.

Professor John W Funder AO

Professor Funder is the Director of the Baker Medical Research Institute and a professor at the Department of Medicine, Monash University. He is also Chair of the Board of the Victorian Health Promotion Foundation, Chairman of SANE Australia and Chair of the Executive Committee of the international Society of Endocrinology. Professor Funder has been a member of numerous committees, including several of the National Health and Medical Research Council. In January 1998 he was made an Officer of the Order of Australia (AO), for his services to medicine and health public policy.

Professor Merilyn Sleigh

Professor Sleigh was appointed Dean, Faculty of the School of Life Sciences, University of New South Wales in 1997. From 1993 to 1997, she was Pharmaceutical Research and Development Director at Peptech Ltd, a biotechnology company. This included managing R&D, intellectual

property and technology commercialisation. From 1988 till joining Peptech, she was Assistant Chief of Division of the CSIRO Division of Biomolecular Engineering. Professor Sleigh carried out research for two years with the pharmaceutical company, Riker, after graduating in Pharmacology prior to joining CSIRO in 1970.

Mr Michael Kimber

Mr Kimber is an independent consultant and the Australian Pharmaceutical Manufacturers Association representative on the Therapeutic Goods Committee. He joined Astra Pharmaceuticals Pty Ltd (Australia) in 1981 as Operations Manager, became Director of Manufacturing in 1983 and was appointed Deputy Managing Director in 1993. He retired last year. From 1972–78 he was Plant Manager with Sterling Drug (South Africa) Pty Ltd, followed by three years as Managing Director.

Mr Robert Bowen

Mr Bowen is currently managing the AusIndustry Business Networks Program in Queensland. He has a background in the pharmaceutical and biotechnology industries. He was General Manager of Agen Ltd, a biotechnology company, and prior to that Director of Operations between 1989–95. From 1984 to 1989, Mr Bowen was with Rhone Poulenc Australia, first as Operations Manager, then as Corporate Development Manager, a member of the group's executive management of pharmaceutical business, including clinical trials and Australian registration.

Mr Graham Glenn

Mr Glenn has been Chair of the Pharmaceutical Benefits Pricing Authority (PBPA) since 1992. The PBPA has had responsibility for managing the Factor f scheme of the Pharmaceutical Industry Development Program. He has held senior positions in public sector areas, including the Chair of the Safety, Rehabilitation and Compensation Commission and, Secretary of the Departments of Industrial Relations and Administrative Services.

Dr Peter MacIsaac

Dr MacIsaac, a Fellow of the Royal Australian College of General Practitioners, has recently joined the Department of Health and Aged Care to provide advice on a broad range of clinical, administrative and academic areas. Dr MacIsaac has worked as a general medical practitioner in regional Victoria and was the foundation Director of the West Victorian Division of General Practice, responsible for identifying local GP and community needs for the integration of GPs into the broader health system. He has also been a Senior Lecturer in Epidemiology at the University of Newcastle.

Appendix 3

Assessment Panel's Terms of Reference

The PIIP Assessment Body will make recommendations to the Minister for Industry, Science and Tourism on which the Minister will base his or her decision as to which applicants will be offered participation in the PIIP and the level of funding to be offered.

The Assessment Panel will make a series of recommendations consistent with the description of the assessment process in the PIIP Supplementary Guidelines.

In respect of the Minister's initial round of offers, the Assessment Panel will make recommendations on:

- The eligibility of companies which have applied for participation in the PIIP.
    - Whether they meet the Corporations Law requirements of the Program.
    - Whether they propose to undertake eligibility activity, as defined in the PIIP Guidelines.
    - Whether, should they participate in the PIIP, they would have the ability to apply payments as price increases to eligible products, as defined in the PIIP Guidelines.
- The eligibility of activities proposed in Production Value Added activity targets.
    - Whether proposed activities related to 'Pharmaceutical Benefit Scheme Like' products should be included as eligible activity.
    - Whether proposed activities related to over-the-counter (OTC) products should be included as eligible activity.
    - Whether proposed active ingredient manufacturing activities should be included as eligible activity.
- The eligibility of activities proposed in Research and Development (R&D) activity targets.
    - Whether proposed OTC R&D activities should be included as eligible activity.
    - Whether the activities meet the definition of R&D in the PIIP Guidelines.
- The relative merit of applications which will be expressed in the form of a ranking in terms of merit of all applications according to agreed methodology.

- The applicants which should be made offers to participate in the PIIP at this time and the level of funding they should be offered.

In respect of any subsequent consideration of rounds of offers by the Minister, the Assessment Panel will recommend:

- Whether there should be any further offer/s of participation made.
    - If not, the Panel will recommend the details, agreed with applicants, which should be publicly released relating to individual PIIP participants and the feedback which should be provided to unsuccessful applicants.
    - If there are to be further offers, based on the ranking of applicants previously recommended, which applicants should be made offers to participate in the PIIP at this time and the level of funding they should be offered.
        * Should the outstanding funding be less than the entitlements of the next ranked applicant, the Panel's recommendation may also include a subset of the applicant's activity on which entitlements could be based

In relation to all recommendations, the Assessment Panel must provide documented reasons for its recommendations.

Should further applications be called for during the course of the PIIP, the Assessment Panel will be reconvened where necessary to make further recommendation to the Minister.

Appendix 4

Management Committee Terms of Reference

The Pharmaceutical Industry Investment Program (PIIP) has been designed to compensate, in part for the impact on activity of the Government exercising its monopsony purchasing power under the Pharmaceutical Benefits Scheme. The scheme will operate for five years, beginning in July 1999 and finishing in June 2004. Funding of $300 million has been allocated to the PIIP.

Entry to the scheme will be competitive, based on an assessment of the relative merits of broad investment and activity programs proposed by companies. Companies will become entitled to higher prices under the scheme by increasing either or both of their Production Value Added (PVA) and research and development (R&D) activities.

The PIIP Management Committee (the Committee) will provide policy and operational directives to the Assessment Support Team in connection with the assessment of applications for entry to the PIIP.

The advice and directives given by the Committee will be consistent with ensuring that the assessment process is equitable, efficient, transparent, and complies with appropriate Government accountability requirements and consistent with the Assessment Procedures for the Pharmaceutical Industry Investment Program and recommendations made by the Assessment Panel.

The Committee will provide guidance on engaging contractors, if necessary, to provide advice and/or undertake specific tasks for the Assessment Support Team in relation to the process. The Committee will provide the Assessment Support Team with a critique concerning such advice and/or tasks to be brought to the notice of Panel members.

The Committee, in consultation with the Assessment Panel, will closely monitor the application of the assessment methodology and, if deemed necessary, will have the capacity to alter the assessment procedures and methodologies (as documented in the Assessment Procedures for the Pharmaceutical Industry Investment Program), consistent with the intent and purpose of the PIIP Guidelines.

The Committee will be responsible for day to day liaison with the Minister's Office concerning PIIP matters. The exception to this will be when the Assessment Panel makes its final recommendations to the Minister concerning which applicants should be granted entry to the PIIP.

The Committee will be responsible for all contact with applicants during the assessment process.

The Committee will also be responsible for all operational matters in relation to the assessment process including, but not limited to:

- developing the procedures to be followed during the process;
- providing/hiring suitable and secure venues for meetings and presentations;
- making travel arrangements for Panel members in connection with their duties;
- ensuring that Panel members are provided with suitable means for securing documents; and
- arranging payment of remuneration in connection with Panel member duties.

Index

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Series Titles

Titles published during the financial year 1998-99

Audit Report No.1 Performance Audit
Corporate Governance Framework
Australian Electoral Commission

Audit Report No.2 Performance Audit
Commercial Support Program
Department of Defence

Audit Report No.3 Performance Audit - Follow-up
Assessable Government Industry Assistance
Australian Taxation Office

Audit Report No.4 Performance Audit
Client Service Initiatives
Australian Trade Commission

Audit Report No.5 Performance Audit
Commonwealth Agencies' Security Preparations for the Sydney 2000 Olympics

Audit Report No.6 Audit Activity Report
Audit Activity Report: January to June 1998
Summary of Outcomes

Audit Report No.7 Performance Audit
Management of the Implementation of the New Employment Services Market
Department of Employment, Education, Training, and Youth Affairs

Audit Report No.8 Performance Audit
Safeguarding Our National Collections

Audit Report No.9 Performance Audit
Accountability and Performance Information
Australian Sports Commission

Audit Report No.10 Performance Audit
Sale of One-third of Telstra

Audit Report No.11 Performance Audit
OGIT and FedLink Infrastructure
Office of Government Information Technology

Audit Report No.12 Performance Audit
Taxation Reform
Community Education and Information Programme

Audit Report No.13 Performance Audit
Aboriginal and Torres Strait Islander Health Program
Department of Health and Aged Care

Audit Report No.14 Performance Audit
Prescribed Payments System
Australian Taxation Office

Audit Report No.15 Performance Audit
Postal Operations
Australian Customs Service

Audit Report No.16 Performance Audit
Aviation Security in Australia
Department of Transport and Regional Services

Audit Report No.17 Performance Audit
Acquisition of Aerospace Simulators
Department of Defence

Audit Report No.18 Performance Audit
Accounting for Aid–The Management of Funding to Non-Government Organisations
Follow-up Audit
Australian Agency for International Development (AusAID)

Audit Report No.19 Performance Audit
The Planning of Aged Care
Department of Health and Aged Care

Audit Report No.20 Financial Statement Audit
Audits of the Financial Statements of Commonwealth Entities for the Period Ended 30 June 1998
Summary of Results and Financial Outcomes

Audit Report No.21 Financial Control and Administration Audit
Costing of Services

Audit Report No.22 Performance Audit
Getting Over the Line: Selected Commonwealth Bodies' Management of the Year 2000 Problem

Audit Report No.23 Performance Audit
Accountability and Oversight Arrangements for Statutory Bodies in the Former Primary Industries and Energy Portfolio

Audit Report No.24–27 Performance Audit
DAS Business Unit Sales
No.24 *Sales Management*
No.25 *DASFLEET Sale*
No.26 *Sale of Works Australia*
No.27 *Sale of DAS Interiors Australia*

Audit Report No.28 Performance Audit
Sale of SA Rail, Tasrail and Pax Rail

Audit Report No.29 Performance Audit
Provision of Migrant Services by DIMA
Department of Immigration and Multicultural Affairs

Audit Report No.30 Performance Audit
The Use and Operation of Performance Information in the Service Level Agreements
Department of Social Security
Department of Employment, Education, Training and Youth Affairs
Centrelink

Audit Report No.31 Performance Audit
The Management of Performance Information for Special Purpose Payments—The State of Play

Audit Report No.32 Performance Audit
Management of Parliamentary Workflow

Audit Report No.33 Audit Activity Report
Audit Activity Report: July to December 1998
Summary of Outcomes

Audit Report No.34 Performance Audit
Fringe Benefits Tax
Australian Taxation Office

Audit Report No.35 Performance Audit
The Service Pension
Department of Veterans' Affairs

Audit Report No.36 Performance Audit
Pay-As-You-Earn Taxation—Administration of Employer Responsibilities
Australian Taxation Office

Audit Report No.37 Performance Audit
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