The Auditor-General
Audit Report No.44 2005–06
Performance Audit

Selected Measures for Managing Subsidised Drug Use in the Pharmaceutical Benefits Scheme

Department of Health and Ageing

Australian National Audit Office

ISSN 1036–7632

ISBN 0 642 80906 2

Australian National
Audit Office

Canberra ACT
1 June 2006

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in the Department of Health and Ageing 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 *Selected Measures for Managing Subsidised Drug Use in the Pharmaceutical Benefits Scheme.*

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.

For further information contact:
The Publications Manager
Australian National Audit Office
GPO Box 707
Canberra ACT 2601

Telephone: **(02) 6203 7505**
Fax: **(02) 6203 7519**
Email: **webmaster@anao.gov.au**

ANAO audit reports and information about the ANAO are available at our internet address:

http://www.anao.gov.au

Audit Team

Paul Nicoll
Deborah Jackson
Andrea Donaldson

Contents

Abbreviations

ANAO	Australian National Audit Office
ARTG	Australian Register of Therapeutic Goods
ATC	Anatomical Therapeutic Chemical (classification system)
AUSFTA	Australia-United States Free Trade Agreement
DUSC	Drug Utilisation Sub-Committee
ESC	Economics Sub-Committee
Guidelines	*Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC*
Health	Department of Health and Ageing
HSD	Highly Specialised Drugs
Minister	Minister for Health and Ageing
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
PES	Pharmaceutical Evaluation Section
PvA	Predicted Versus Actual Systematic Analysis
RSA	Risk Sharing Agreement
RWG	Restrictions Working Group
Schedule	*Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners*
TGA	Therapeutic Goods Administration

Summary and Recommendations

Summary

About the Pharmaceutical Benefits Scheme

1. The purpose of the Pharmaceutical Benefits Scheme (PBS) is to provide Australians with timely, reliable and affordable access to necessary and cost-effective drugs. The PBS is administered by the Department of Health and Ageing (Health) according to the *National Health Act 1953* and the *National Health (Pharmaceutical Benefits) Regulations 1960*. There were 600 drugs, listed as 1579 items, on the *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners* (Schedule) in March 2006.[1] An item is a form or strength of a particular drug.

2. Following approval by the Therapeutic Goods Administration (TGA) for use of a drug in Australia, the process for listing a drug on the PBS is complex and involves, *inter alia*, the drug's sponsor (usually a pharmaceutical company), Health, several expert committees, and the Minister for Health and Ageing. The expert committees are the Pharmaceutical Benefits Advisory Committee (PBAC), which makes recommendations to the Minister about the listing of drugs, and its two sub-committees—the Drug Utilisation Sub-Committee (DUSC) and the Economics Sub-Committee (ESC)—and the Pharmaceutical Benefits Pricing Authority (PBPA).

3. In 2006–07, the PBS budget is $6.8 billion, which will subsidise around 170 million prescriptions. The rate of growth in PBS expenditure is expected to be around 2.8 per cent in 2005–06 and 7.3 per cent in 2006–07, down from an average of 10.2 per cent per year over the past 10 years. Several government initiatives have been put in place to slow the PBS expenditure growth rate, including initiatives to address the risk that PBS subsidised drugs will be used outside their subsidy conditions.[2]

---

[1] Excludes section 100 drugs. Section 100 of the *National Health Act 1953* applies to drugs that are distributed under alternative arrangements, such as highly specialised drugs and drugs distributed though the Human Growth Hormone Program.

[2] A drug can be prescribed for any medical condition approved by the TGA. A drug is generally listed on the PBS for specific conditions, which may be a sub-set of the conditions approved by the TGA. The PBS only subsidises prescriptions that comply with the drug's PBS listing conditions. Therefore, use outside subsidy condition occurs when a Commonwealth subsidy is claimed for a prescription that does not comply with the drug's PBS listing.

4. As part of its risk management approach to administering the PBS, Health employs a number of measures to reduce that risk. These measures include:

- restrictions—limitations on the listing of drugs to prescribed therapeutic uses. For example, on the PBS, Olanzapine is restricted to use for schizophrenia and maintenance treatment of bipolar I disorder;[3]
- authority required restrictions—similar to normal restrictions but prescribers must obtain approval from Medicare Australia prior to prescribing; and
- risk sharing agreements—the Commonwealth and the drug's sponsor agree to share the risk of a drug costing the PBS more than estimated. For example, the Commonwealth agrees to subsidise a drug providing the sponsor agrees to limit sales of the subsidised drug to a certain amount. In addition, the Commonwealth may require the sponsor to rebate a percentage of the sales of a drug in excess of an agreed amount.

Currently over half of the items listed on the PBS are subject to one or more of the above three measures.

Audit objective and methodology

5. The objective of the audit was to examine how effectively Health manages the risk of PBS drugs not being used according to PBS subsidy conditions. The audit examined two areas:

- during listing, how Health identified and implemented measures to decrease the risks of PBS drugs being used outside subsidy conditions; and
- following listing, how Health confirmed that usage and expenditure on PBS drugs was consistent with estimates.

6. The report examines selected approaches used by Health, which have evolved in recent years, to manage the risk of PBS drugs being used outside subsidy conditions. The report also acknowledges and describes the role of the expert committees.

---

[3] Department of Health and Ageing, December 2005, *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners,* Health, p.270.

7. The scope of the audit was limited to PBS drugs for which Health pays a subsidy. The audit did not examine Health's role in educating consumers, prescribers, and other health professionals, or the implications of the Australia–United States Free Trade Agreement for the PBS. Additionally, the ANAO did not form an opinion on the success of Medicare Australia's compliance role.

8. To form an opinion against the audit objective, the ANAO interviewed Health personnel, committee members and stakeholders, examined relevant documents and files, analysed drug usage and expenditure data, and attended a number of committee meetings. To assist the audit process, the ANAO selected a sample of eight drugs. The drugs were selected due to their high cost to the PBS and/or high usage, or because the drug has had a particularly interesting PBS history. The sample is not representative of all drugs on the PBS. In 2004–05, 15.3 million prescriptions were written for these eight drugs, with the Government subsidy totalling $1.05 billion.

Overall audit conclusion

9. The ANAO concluded that, while the Department of Health and Ageing's (Health's) management of the risk of Pharmaceutical Benefits Scheme (PBS) drugs being used outside subsidy conditions is reasonable, some improvements in Health's administration would strengthen its management of this risk.

10. Health has put in place measures to control PBS expenditure in recent years, and expects growth to decrease, by an average of three percentage points over the past 10 years, to 7.3 per cent in 2006–07.

11. While Health is increasingly using restrictions, authority required restrictions and risk sharing agreements to control expenditure and decrease the risk of PBS drugs being used outside subsidy conditions, it does not use specific criteria to guide its selection of these measures. Also, Health has not reviewed the effectiveness of these measures. Such a review would enable Health to be better informed on the impact of each type of measure on the use of drugs outside subsidy conditions, and the contribution the measures have made to containing Commonwealth expenditure or slowing the PBS expenditure growth rate.

12. Health has reasonable processes to examine and confirm the relevance and accuracy of estimates of intended use and cost when drugs are first listed. Nevertheless, two factors impair the effectiveness of these processes. Firstly,

incomplete and inaccurate data available to Health during the listing process may result in actual usage and cost differing from estimates. Secondly, the absence of a complete and accurate PBS dataset on the usage of PBS subsidised drugs hampers Health's monitoring and investigation role following listing.

13. Health's monitoring of PBS drugs with risk sharing agreements is satisfactory. However, for PBS drugs without a risk sharing agreement, Health's investigation and ongoing monitoring of usage and expenditure is limited. In this context, the ANAO acknowledges the constraints on Health in altering a drug's listing after inclusion on the PBS.

14. The ANAO made two recommendations to improve Health's management of the risk of PBS drugs being used outside their subsidy conditions.

Key Findings

PBS Expenditure (Chapter 2)

15. From 1998–99 to 2003–04 actual expenditure on the Pharmaceutical Benefits Scheme (PBS) was greater than budgeted. In 2004–05, this trend reversed and expenditure was 3.7 per cent less than estimated. The Department of Health and Ageing (Health) expects this shift to continue for 2005–06. The rate of growth in Commonwealth expenditure on the PBS is down from an average of 10.2 per cent over the past 10 years, to an estimated 2.8 per cent in 2005–06 and 7.3 per cent in 2006–07. Initiatives such as the use of risk sharing agreements, closer scrutiny of drug costs and usage estimates, and the increased role of the Drug Utilisation Sub-Committee (DUSC) in investigating differences in estimated and actual usage have been put in place to control the PBS's growth rate.

Restrictions and Risk Sharing Agreements (Chapter 3)

16. The use of PBS subsidised drugs outside their subsidised conditions increases Commonwealth expenditure on the PBS. There are a number of factors that increase the risk of subsidised drugs being used outside subsidy conditions. These factors include when there is a gap between therapeutic uses approved by the Therapeutic Goods Administration (TGA) and the drug's listing, promotion by the drug's sponsor, and consumer demand. Health uses several measures to address this risk, including restrictions, authority required restrictions, and risk sharing agreements. While Health's practice may indicate, for some drugs or classes of drugs, the use of a particular approach, such as a risk sharing agreement for very high cost drugs, Health does not have specific criteria to guide its selection of particular measure(s).

Restrictions

17. Of the 1 579 items on the PBS, 59 per cent (924 items) are restricted. The complexity of restrictions, including the number of words required to define conditions, is increasing, as is the proportion of restricted and authority required items on the PBS.

18. Complex or contentious restrictions are considered by the Restrictions Working Group (RWG) and with relevant specialist groups. Generally, over time, restrictions are relaxed or conditions are added. Often when a restriction is relaxed or discontinued, Health negotiates a price reduction with the drug's

sponsor. The ANAO found that the effectiveness of restrictions is reduced by several factors including ambiguity of their wording and prescriber intent. Research commissioned by Medicare Australia found that prescribing outside restrictions was not uncommon.

Authority required restrictions

19. Authority required restrictions apply to 426 (27 per cent) of PBS items, an increase of seven percentage points in the past five years. Prescribers know what questions they will be asked when applying for approval to prescribe authority restricted drugs. The ANAO has been advised that prescribers are, therefore, in a position to influence the approval. Other prescribers may consider the system too time-consuming or complex, and therefore they prescribe other drugs which do not require Medicare Australia's approval. This may result in patients receiving sub-optimal medication or the patients most in need of the drugs not receiving them. Nevertheless, authority required restrictions are considered to be more effective than general restrictions.

Risk sharing agreements

20. Health is also increasingly using risk sharing agreements, with 14 in place to November 2005 and a further nine being negotiated with sponsors. The ANAO found that Health's approach to negotiating risk sharing agreements has improved over time, and they are now negotiated on the basis of likely expected usage of each subsidised drug. Nevertheless, Health does not expect the prescription volume and dollar caps of the majority of risk sharing agreements to be reached in the current year. This indicates that there is potential for Health to propose more realistic caps when negotiating with sponsors.

Reviewing the measures

21. Health has not reviewed the effectiveness of risk sharing agreements, restrictions or authority required restrictions in decreasing inappropriate Commonwealth expenditure on the PBS.

Estimating Usage and Cost (Chapter 4)

22. During listing, Health and its expert committees examine estimates of a drug's usage and cost. This process is complex and involves a number of different stages and participants, including Health's committees and their secretariats. DUSC, which has primary responsibility for evaluating usage

estimates, does not review every major submission, using criteria to determine which submissions to examine. The Economics Sub-Committee (ESC) reviews every submission.

23. The ANAO found that Health's iterative process for finalising drug usage estimates was satisfactory. Health assured itself that the information in the submissions of drug sponsors was relevant and appropriate and committee discussions appeared to be full and robust.

24. However, estimates of a drug's cost and usage can only be as accurate as the data used to calculate the estimates. There are a number of difficulties in obtaining accurate and reliable data prior to listing a drug. These difficulties include the lack of epidemiological data for previously untreated or rare conditions, small clinical trials, measuring unmet clinical need and determining market share.

25. In the absence of definitive data, Health and the Pharmaceutical Benefits Advisory Committee (PBAC) take a risk management approach that involves finding the balance between recommending listing on the basis of incomplete data so prescribers can meet their patient's clinical need, and delaying listing until more conclusive data is available.

Monitoring Usage and Cost (Chapter 5)

26. Health's monitoring of PBS drug usage and cost is generally limited to monitoring those drugs with risk sharing agreements. The ANAO found that the monitoring of risk sharing agreements has improved recently and is satisfactory.

27. Health's only systematic investigation of drug usage is through DUSC's Predicted Versus Actual Systematic Analysis (PvA). Health's procedures state that it conducts PvAs on all new drugs and on drugs that exhibit major changes within a defined time period. However, the ANAO found that, of the 19 new drugs listed in 2003–04, seven (37 per cent) had not been the subject of a PvA at the time of the audit fieldwork. In not completing PvAs as specified, Health is not conducting timely analysis on the use of all new drugs listed on the PBS.

28. Of the eight drugs in the ANAO's sample, six were the subject of a PvA since 2003. In examining these PvAs the ANAO found little examination or analysis of differences between estimated and actual drug use. The ANAO observed that the majority of PvAs did not make a valid comparison between

predicted and actual drug usage and expenditure and that there was no significant examination of reasons for differences between estimated and actual data. For example, the PvA for one drug in the ANAO's sample found a 500 per cent difference between predicted and actual cost, but with no documented action to address this finding. The ANAO noted that the PvAs completed 24 months after listing were more detailed.

29. Furthermore, the ANAO found that Health's response to PvA results was limited. Results are discussed at DUSC meetings and further action may be taken, such as informing the National Prescribing Service or inviting industry comment. The ANAO found that, for the PvAs examined, no changes were subsequently made to the drug's listing. That is, action was not taken in response to the findings of the PvA.

30. Health's efforts to monitor and investigate drug usage and cost is hindered by the lack of a complete PBS dataset on the usage of PBS subsidised drugs. Issues around obtaining and using a complete dataset include the limited availability of data on drugs prescribed in public hospitals, the lack of data on drugs retailing for an amount below the PBS co-payment amount, and legal limitations on Health and Medicare Australia linking diagnostic and prescribing data.

Department of Health and Ageing's Response

The Department welcomes the ANAO report as a useful assessment of its management of a very complex scheme, and as providing helpful recommendations for further improvement.

The Department notes the report's overall conclusion that '…Health's management of the risk of Pharmaceutical Benefits Scheme (PBS) drugs being used outside subsidy conditions is reasonable…'.

The Department is supportive of the two recommendations.

Recommendations

Recommendation No.1

Para. 3.41

The ANAO recommends that the Department of Health and Ageing (Health):

- develop and implement criteria to guide its selection of measures to control the use of drugs when listing or altering the listing conditions of existing drugs on the Pharmaceutical Benefits Scheme; and
- periodically review the success of these measures;

Health's response: Agreed.

Recommendation No.2

Para. 5.24

To maximise the value of the Drug Utilisation Sub-Committee's (DUSC's) predicted versus actual systematic analysis (PvA), the ANAO recommends that Health:

- require DUSC to compare the actual and predicted use of all major drugs and any drugs with significant changes to usage 12 months after listing, and again at 24 months if necessary; and
- ensure DUSC follows Health's procedures for conducting PvAs.

Health's response: Agreed.

Audit Findings and Conclusions

1. Introduction

This chapter summarises the relevant features of the Pharmaceutical Benefits Scheme, and provides a background to the audit, including the audit objective, approach and methodology.

The Pharmaceutical Benefits Scheme

1.1 The Pharmaceutical Benefits Scheme (PBS) is administered by the Department of Heath and Ageing (Health). The purpose of the PBS is to provide Australians with timely, reliable and affordable access to necessary and cost-effective drugs. The PBS is administered according to the *National Health Act 1953* and the *National Health (Pharmaceutical Benefits) Regulations 1960*.

1.2 Through the PBS, the Commonwealth pays a subsidy for drugs listed on the Schedule.[4,5] In 2006–07, the PBS budget is $6.8 billion. As at March 2006 there were 600 drugs, listed as 1579 items, on the Schedule.[6] The PBS annually subsidises about 170 million[7] pharmaceutical prescriptions, approximately 80 per cent of total prescriptions dispensed in Australia.

Listing drugs on the PBS

1.3 The Therapeutic Goods Authority (TGA), which is part of Health, administers the *Therapeutic Goods Act 1989*. The objective of the *Therapeutic Goods Act 1989* is to provide a national system of controls to regulate the quality, safety, efficacy and timely availability of therapeutic goods in Australia.[8] Before therapeutic goods can be supplied in Australia they must be entered on the Australian Register of Therapeutic Goods (ARTG). Following

---

4 The Commonwealth pays pharmaceutical benefits in accordance with sections 85 and 100 of Part VII of the *National Health Act 1953*. Section 85 applies to the vast majority of PBS drugs, while section 100 applies to drugs distributed under alternative arrangements (for example: highly specialised drugs prescribed by specialists attached to specialist hospital units; and drugs distributed through the Human Growth Hormone Program and the Opiate Dependence Treatment Program).

5 The Schedule is available at: <www.health.gov.au/internet/wcms/publishing.nsf/Content/Schedule+of+Pharmaceutical+Benefits-1>.

6 A drug is a chemical entity. Each drug may have one or more branded products. For example, Paracetamol is marketed by several pharmaceutical companies under different product names. An item is a form or strength of a particular drug. For example, Paracetamol is available through the PBS in several forms, including a 500 mg tablet and an orally administered liquid. The number of drugs and items excludes section 100 drugs.

7 Excludes prescriptions for section 100 drugs.

8 *Therapeutic Goods Act 1989*, Section 4(1)(a).

registration of a drug on the ARTG, a drug company can apply to have that drug listed on the PBS for treatment of all or a selection of the conditions registered by the TGA. For example, the TGA approval for Alendronate for osteoporosis[9] is wider than the PBS listing. Alendronate is listed on the PBS for the initial treatment of patients with osteoporosis who have suffered a fracture due to minimal trauma. The TGA approval does not require patients to have a fracture before being prescribed Alendronate.

1.4 The process for listing a drug on the PBS is complex and involves a number of parties, including:

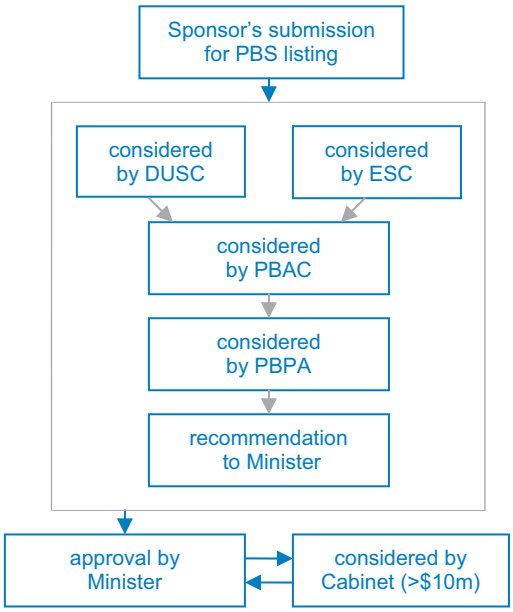
- the drug's sponsor (usually a pharmaceutical company);
- Health;
- Pharmaceutical Benefits Advisory Committee (PBAC);
- Drug Utilisation Sub-Committee (DUSC);
- Economics Sub-Committee (ESC);
- Pharmaceutical Benefits Pricing Authority (PBPA);
- the Minister for Health and Ageing; and
- Cabinet.

1.5 Figure 1.1 presents an overview of the process for listing a new drug on the PBS.

[9] Alendronate is also approved by the TGA and listed on the PBS for the treatment of Paget's disease of bone.

Figure 1.1

The PBS listing process (an overview)



[1] As discussed in Chapter 4, DUSC does not consider all submissions.

Source: ANAO analysis.

1.6 The roles of the PBAC, DUSC and ESC are described in *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC* (Guidelines) as follows:

> The Pharmaceutical Benefits Advisory Committee (PBAC) is established under the *National Health Act 1953* to make recommendations to the Minister for Health about which drugs and medicinal preparations should be available as pharmaceutical benefits, and to advise the Minister about any other matter relating to the Pharmaceutical Benefits Scheme (PBS) which is referred to it by the Minister. The Committee is also required by the Act to consider the effectiveness and cost of a proposed benefit compared to other therapies.
>
> The Drug Utilisation Sub-Committee monitors the patterns and trends of drug use and makes such utilisation data available publicly.
>
> The Economics Sub-Committee advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to the PBAC.[10]

[10] Department of Health and Ageing, September 2002, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC*, Health, pp.2-3.

1.7 The PBPA is an independent non-statutory body established by Cabinet in 1988. The role of the PBPA is to recommend to the Minister prices for new drugs and to review prices of PBS listed drugs. The PBAC, its sub-committees, and the PBPA meet three times per year. Health provides the secretariat for each of these committees and the PBPA.

1.8 To have a drug listed on the PBS, or change a drug's listing, the drug's sponsor must make a submission to the PBAC. Submissions are either major or minor. Generally, a major submission is required to list a new drug or to request a significant change to a listed drug. A minor submission is required if a minor change is requested, such as a change to the maximum quantity of a listed drug that can be prescribed, or to clarify the wording of a restriction but not alter the drug's intended use. The contents of major and minor submissions are discussed in more detail in Appendix 1.

1.9 Health and its expert committees use a number of measures to control the prescribing of PBS drugs for conditions not included in the Schedule. These measures include restricting the use of drugs to specific conditions and risk sharing agreements between Health and drug sponsors. Of the 1579 items listed on the Schedule, over half are subject to one or more of these measures.

1.10 The various parties involved in the PBS process have different and, often, competing objectives. Health's objective in negotiating these measures with sponsors is to contain prescribing of PBS drugs to subsidy conditions, to maximise value for PBS expenditure, and to control the cost of the PBS. Therefore, high cost drugs are more likely to be subject to controlling measures than low cost drugs. The sponsors, on the other hand, are private sector entities that provide pharmaceutical products with health benefits, while seeking to provide returns on their shareholders' investments. As such, their general objective will be to pursue a high level of subsidy while limiting the number and type of measures Health uses to control prescribing. At the same time, drugs are often listed in an environment of high prescriber and consumer expectation and demand.

1.11 In response to discussions with Health following the ANAO's fieldwork, Health advised the following.

> The PBS process has a number of interacting characteristics that reflect a process of continuous learning and improvement. There is a multi-step process involving Health, its expert committees and the sponsors that supports exchange of information and explores ways to apply the risk measures available at the micro level for each proposed drug listing. New proposed drug listings that are expected to cost the PBS more than $10 million per annum are required to be considered by Cabinet. Thus there are extra steps for such high cost and potentially high risk listings that include coordination across relevant Ministers and their portfolios in finalising the Cabinet Submission.
>
> This entire process is supported by an evolving understanding of how best to access, present and interpret relevant information, including information which predicts usage and expenditure patterns should requested listing on the Schedule be implemented. Inevitably these processes can sometimes identify new or improved ways to manage risk that themselves become part of the framework in which listings occur.
>
> At a more strategic level, information about which risk mitigation measures are most effective for particular types of listings or populations of drugs and the level of sophistication applied to assessing risk of particular listings, continues to build.
>
> Recent budgets have seen a number of measures that strengthen and enhance PBS processes. For example, the 2002–03 Federal Budget introduced a series of programs aimed at ensuring that medicines are prescribed in accordance with PBS requirements and that predictions of costs for new high cost listings are independently verified. These measures are in the process of being implemented, and in monitoring their effectiveness, further findings emerge as to 'what works'.

Accessing PBS drugs

1.12 Once drugs are listed on the PBS they are available to Australians at a subsidised cost. Patients contribute a co-payment, which is paid to the pharmacist when the prescription is filled. Under the PBS safety net arrangements, when a concession card holder's co-payments reach a certain amount each year, prescriptions will be free for the rest of the year. When general patients' (patients that do not hold concession cards) co-payments reach the threshold amount they pay the equivalent of the concession card

holder co-payment for prescriptions for the rest of that year. The current co-payment and safety net amounts are presented in Figure 1.2.

Figure 1.2

PBS co-payments and safety net

	Patient Co-payment	Safety Net Threshold
General Consumers	$29.50	$960.10
Concession Card Holders	$4.70	$253.80

Note: Excludes any product premiums applied by manufacturers.

Source: Department of Health and Ageing, *Frequently Asked Questions About the PBS*, <www.health.gov.au> accessed 31 March 2006.

Previous audit coverage

1.13 The ANAO audits the financial statements of Health annually. Other ANAO performance audits broadly relevant to the PBS include[11]:

- *Regulation of Non-prescription Medicinal Products*, Department of Health and Ageing, Therapeutic Goods Administration, No. 18, 2004–05; and
- *Pharmaceutical Benefits Scheme*, Department of Health and Family Services, No. 12, 1997–98.

The audit

Audit objective and scope

1.14 The objective of the audit was to examine how effectively Health manages the risk of PBS drugs not being used according to PBS subsidy conditions.

1.15 The audit examined two areas:

- during listing, how Health identified and implemented measures to decrease the risks of PBS drugs being used outside subsidy conditions; and
- following listing, how Health confirmed that usage and expenditure on PBS drugs was consistent with estimates.

[11] Audits completed since 1997-98.

1.16 The report examines selected approaches used by Health, which have evolved in recent years, to manage the risk of PBS drugs being used outside subsidy conditions. The report also acknowledges and describes the role of the expert committees.

1.17 The audit was limited to PBS drugs for which Health pays a subsidy. The audit did not examine the use of drugs in public hospitals for which the Commonwealth does not pay a subsidy through the PBS. The Australia–United States Free Trade Agreement (AUSFTA), which came into force on 1 January 2005, covers the PBS. However, the ANAO did not examine the provisions of the AUSFTA since it was still in the early stages of implementation and outside the scope of this audit.

1.18 Additionally, the audit did not examine Health's role in educating consumers, prescribers, and other health professionals, about the PBS or the appropriate use of PBS drugs. However, the ANAO recognises that education is an important element of Health's approach to managing the PBS, and specifically, to managing the risk of PBS subsidised drugs being used outside PBS subsidy conditions. Medicare Australia's compliance role is described in Chapter 5. The ANAO did not form an opinion on the success of this function.

1.19 The audit was conducted in accordance with ANAO Auditing Standards at a cost of $385 000.

Audit methodology

1.20 To form an opinion against the audit objective, the ANAO interviewed key Health and Medicare Australia[12] personnel; examined Health's documents, data, files, and website; analysed drug usage and expenditure data; interviewed stakeholders; and reviewed relevant literature. The ANAO also interviewed members of the PBAC and its sub-committees, and the PBPA; observed one PBAC, one DUSC and one ESC meeting; and examined minutes of PBAC, sub-committees and PBPA meetings.

1.21 To assist the audit process, the ANAO selected a sample of eight drugs. These are shown in Figure 1.3. The eight drugs in the sample were selected due to their high cost to the PBS and/or high usage, or because the drug has had a particularly interesting PBS history. Each drug is produced by a different manufacturer and is from a different therapeutic group. The sample drugs are

[12] Formerly the Health Insurance Commission.

from eight of the 14 main Anatomical Therapeutic Chemical (ATC) groups[13] and, generally, cover 19 indications. The drugs in the sample are subject to a range of measures to decrease the risk of use outside subsidy condition, but include one drug (Latanoprost) with no measures. The sample is not representative of all drugs on the PBS. In 2004–05, 15.3 million prescriptions were written for these eight drugs. In that year the Government subsidy for the eight drugs was $1.05 billion.

[13] The Anatomical Therapeutic Chemical (ATC) classification system is an internationally recognised method to divide drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. There are 14 therapeutic groups at the highest level (see Appendix 2).

Figure 1.3

ANAO sample

Drug	Year Listed	Indication (Restriction)	Therapeutic Group (ATC Level 1 & 2)	Usage (prescriptions) 2004–05	PBS Cost 2004–05 ($)
Alendronate Sodium (Fosamax)	1996	Established osteoporosis in patients with fracture due to minimal trauma and Paget's disease	1. Musculo-Skeletal System 2. Drugs for the Treatment of Bone Diseases	2 116 144	108.6m
Atorvastatin Calcium (Lipitor)	1998	Lipid lowering (subject to General Statement for Lipid Lowering Drugs)	1. Cardiovascular System 2. Serum Lipid Reducing Agents	8 075 206	461.0m
Clopidogrel Hydrogen Sulphate (Iscover & Plavix)	1999	Prevention of symptomatic cerebrovascular and cardiac ischaemic events (under certain conditions)	1. Blood and Blood Forming Organs 2. Antithrombotic Agents	1 810 926	141.9m
Etanercept (Enbrel)	2003	Rheumatoid arthritis, juvenile chronic arthritis and ankylosing spondylitis (each under certain conditions)	1. Antineoplastic and Immunomodulating Agents 2. Immunosuppressive Agents Also: Highly Specialised Drugs Program (s.100 item)	13 717	25.7m
Imatinib (Glivec)	2001	Gastrointestinal stromal tumour and chronic myeloid leukaemia (under certain conditions)	Special Authority Program (s.100 item)	10 291	43.9m
Latanoprost (Xalatan)	1998	Unrestricted (used to treat glaucoma)	1. Sensory Organs 2. Ophthalmologicals	1 523 810	43.5m
Olanzapine (Zyprexa)	1997	Schizophrenia and maintenance treatment of bipolar I disorder	1. Nervous System 2. Psycholeptics	710 628	149.5m
Tiotropium Bromide Monohydrate (Spiriva)	2003	Long term maintenance treatment of bronchospasm and dyspnoea associated with chronic obstructive pulmonary disease	1. Respiratory System 2. Drugs for Obstructive Airway Diseases	1 032 063	75.3m

Note: The name in brackets in the first column is the branded product name for the drug.

Source: ANAO analysis.

Report structure

1.22 This report is divided into five chapters, as follows:

- Chapter 1: Introduction;
- Chapter 2: PBS Expenditure;
- Chapter 3: Restrictions and Risk Sharing Agreements;
- Chapter 4: Estimating Usage and Cost; and
- Chapter 5: Monitoring Usage and Cost.

2. PBS Expenditure

This chapter illustrates the recent growth in the Pharmaceutical Benefits Scheme budget and how the Department of Health and Ageing estimates the budget.

The PBS Model

2.1 The Department of Health and Ageing (Health) has developed a model to estimate the annual Pharmaceutical Benefits Scheme (PBS) budget[14], referred to as the PBS Model. The model separates the data into concessional (Concessional Safety Net) and general (General Safety Net). Health reviews the PBS budget forecasts annually. By applying the model, Health produces monthly forecasts for PBS expenditure and script volumes for five financial years. The model incorporates a number of variables, including adjustments based on actual expenditure, population changes, and changes to Government policy. The model also incorporates the effect of major new listings on the PBS budget. Therefore, when a major new drug, particularly one that is estimated to be costly, is listed on the PBS, the model will be adjusted to reflect that listing and, consequently, the PBS budget forecasts will change. For example, the 2004 model incorporated the drug Etanercept, which was listed in 2003 and was expected to have a significant impact on the cost of the PBS.

2.2 If, however, health professionals do not prescribe a major new drug as estimated, the budget forecasts will be incorrect. For example, if prescribing of a drug was 75 per cent less than its PBS expenditure cap of $55 million in its first year of listing, the impact of the difference between estimated and actual cost of this one drug would be an apparent underspend of $41 million for that year. A further impact of overestimating prescribing is that actual growth in the PBS budget is less than estimated. On the other hand, if a drug is prescribed at levels higher than estimated, the budget forecast will be underestimated. For example, Celecoxib[15] was listed on the PBS in August 2000 and Health estimated that it would cost the Commonwealth $43 million in 2000–01. This figure was exceeded within the first few months of listing, with Celecoxib costing the Commonwealth $161 million in that year.

2.3 Health reviewed its PBS Model, as it was applied to forecasting 1999–2000 and 2000–2001 budget expenditure, in 2002. The review found 'that

[14] The model forecasts expenditure at the Anatomical Therapeutic Chemical (ATC) level 2 for PBS section 85 drugs.

[15] Celebrex is the branded product name for Celecoxib.

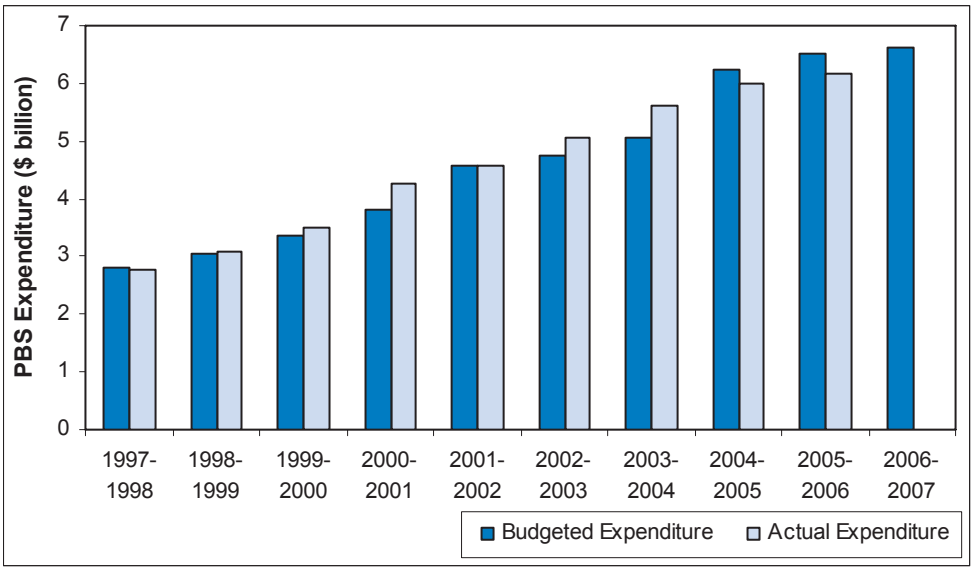
the current forecasting arrangements are generally sound, although improvements can be made in some areas'. Health has since updated the model to reflect the review report's recommendations.

Budget growth

2.4 In 2006–07, the PBS budget is $6.8 billion. Figure 2.1 compares Health's Budget estimates and actual expenditure. In 2000–01 and 2003–04 actual expenditure was over 10 per cent higher than budgeted, which was a difference of $462 million and $542 million respectively. However, in 2004–05 and 2005–06 expenditure was 3.7 per cent ($229 million) and 5.2 per cent ($337 million), respectively, lower than budgeted.

Figure 2.1

PBS budget and expenditure

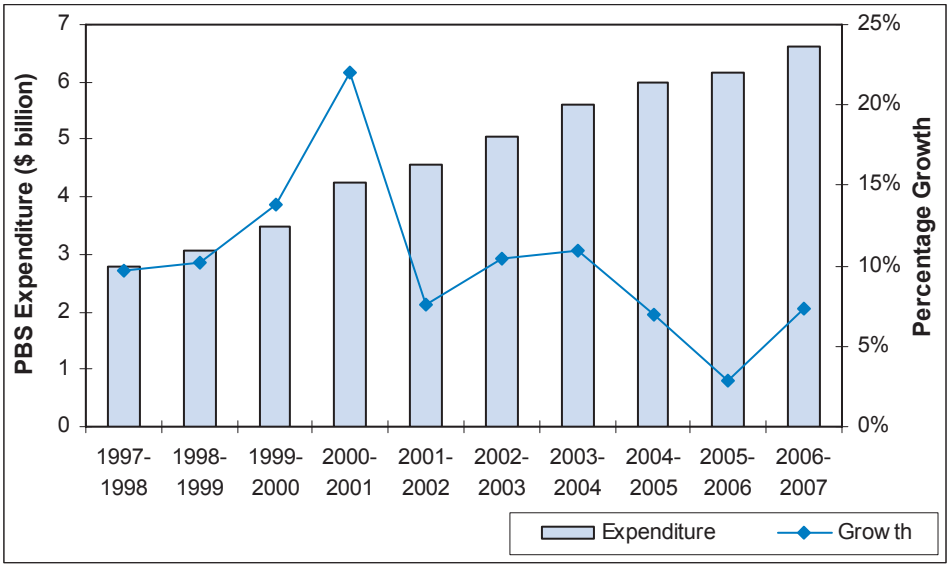


Source: ANAO analysis of Health's Annual Reports 1998–1999 to 2004–2005 and Portfolio Budget Statements 1996–1997 to 2006–2007.

2.5 Over the past 10 years, Commonwealth expenditure on the PBS has grown by an average of 10.2 per cent per year. Growth is expected to be around 2.8 per cent in 2005–06, rising to 7.3 per cent in 2006–07. Figure 2.2 illustrates annual PBS expenditure and growth since 1997–98.

Figure 2.2

PBS expenditure and growth



Note: 1997–98 to 2004–05 figures are actual expenditure; the 2005–2006 figure is estimated actual expenditure, and 2006–2007 is a budget estimate.

Source: ANAO analysis of Health's Annual Reports 1998–1999 to 2004–2005 and Portfolio Budget Statements 2005–2006 and 2006–2007.

2.6 Several government initiatives have been put in place to slow the PBS's growth rate. These initiatives include:

- restrictions;
- authority required restrictions; and
- risk sharing agreements.[16]

[16] These three initiatives are discussed in detail in Chapter 3.

2.7 Additional initiatives, outside the scope of this audit, include:

- Medicare Australia's compliance role, which is discussed in Chapter 5;
- the need to gain Cabinet approval for new drugs or indications with an estimated PBS cost greater than $10 million per year in any year within the first four years of listing;
- increasing the patient co-payment and the safety net threshold;
- greater emphasis on the quality use of drugs[17]; and
- improved communication and education to prescribers and consumers about the PBS.

2.8 The following chapter examines Health's use of restrictions, authority required restrictions, and risk sharing agreements to reduce the risk that PBS drugs will be prescribed outside their subsidy conditions.

---

[17] The quality use of medicines is an objective of the National Medicines Policy and means:

- selecting management options wisely;
- choosing suitable medicines if a medicine is considered necessary; and
- using medicines safely and effectively.

3. Restrictions and Risk Sharing Agreements

This chapter examined three of the measures the Department of Health and Ageing uses to reduce the risk that Pharmaceutical Benefits Scheme drugs will be prescribed outside their subsidy conditions and analyses issues associated with these measures.

Why drugs might be prescribed outside PBS subsidy conditions

3.1 When listing drugs on the Pharmaceutical Benefits Scheme (PBS), or making changes to existing listings, the Department of Health and Ageing (Health) and its committees consider the risk that the drug will be prescribed for therapeutic uses other than those prescribed in the *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners* (Schedule) and for which Health pays a subsidy. There are a number of factors that increase the risk of PBS subsidised drugs being used outside subsidy condition. These factors include:

- when a gap exists between therapeutic uses approved by the Therapeutic Goods Administration (TGA) and therapeutic uses listed on the Schedule;
- when a drug's listing on the PBS is restricted to certain conditions;
- when a drug is listed with an ambiguously worded restriction;
- time, where the potential for use outside subsidy condition increases over time as the drug is shown to be effective for therapeutic uses not included in the PBS listing;
- advertising and promotion by drug sponsors to maximise sales; and
- consumer demand or pressure.

The measures Health adopts to decrease the risk of PBS drugs being prescribed outside subsidy condition

3.2 Health employs a number of approaches to reduce the risk that PBS drugs will be used outside PBS subsidy conditions. The measures examined in this report, which are part of Health's risk management strategy, are listed in Figure 3.1. The measures apply to individual drugs. However, Health

considers measures applying to similar listed drugs when considering submissions for listing or changes to existing listings.

Figure 3.1

Measures to decrease the risk of PBS drugs being used outside subsidy conditions[18]

Chapter of this audit report	Measures used by Health
Chapter 3	Restricting the listing of drugs to prescribed therapeutic uses (restricted benefit)
	Restricting the listing of drugs to prescribed therapeutic uses and requiring that prescribers obtain approval from Medicare Australia prior to prescribing (authority required restrictions and written authority required restrictions) [19]
	Negotiating a risk sharing agreement (RSA) with the sponsor
Chapter 5	Medicare Australia's PBS compliance program
	Health's monitoring of PBS drug usage

Source: ANAO.

3.3 Just under 60 per cent of the items on the Schedule are subject to a restriction, authority required restriction and/or RSA. The prescribing of the other 40 per cent of drugs is not limited. Health uses a number of these measures to control the use of the eight drugs sampled by the ANAO, as shown in Figure 3.2.

[18] Two further measures are Cabinet's consideration of high cost submissions and prescriber education. An April 2002 Government decision requires that all submissions with an estimated Government cost greater than $10 million per year be considered by Cabinet. This audit report does not examine the implementation of that decision further, but notes that it is an important element of a strategy focussing on high cost drugs with the greatest risk to the Government. As mentioned in Chapter 1, prescriber education was outside the scope of this audit and, as such, is not included in this report.

[19] Medicare Australia is a statutory agency that assists Health to implement a range of health programs. The Strategic Partnership Agreement between Health and Medicare Australia outlines roles and responsibilities of both entities. The Pharmaceutical Benefits Scheme is one of the programs covered by the Strategic Partnership Agreement.

Figure 3.2

Measures used for the drugs in the ANAO's sample

Drug	Current Measure		
	Restrictions	*Authority Restrictions*	*Risk Sharing Agreements*
Alendronate	✓	✓	✖
Atorvastatin	✓	✖	✖
Clopidogrel	✓	✓	✖
Etanercept	✓	✓[1]	✓
Imatinib	✓	✓[1]	✓
Latanoprost	✖	✖	✖
Olanzapine	✓	✓	✓
Tiotropium	✓	✖	✖

Note 1: Require written authority.

Source: ANAO analysis.

Restrictions

3.4 A drug with a restricted benefit, or restriction, can only be prescribed under the PBS for those specific therapeutic uses described in the Schedule. Of the 1 579 items on the December 2005 Schedule, 924 (58.5 per cent) are restricted.[20] This includes 426 items that require prior authority from Medicare Australia to prescribe (discussed in the next section). The *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC* (Guidelines) state that the purposes of a restricted benefits (and authority required restrictions) listing are:

- to limit PBS usage so that this is in accordance with the approval and registration granted by the TGA;
- to allow the controlled introduction of a drug in a new therapeutic class;

[20] These data exclude section 100 drugs. All section 100 drugs are restricted.

- to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical, cost-effectiveness, or other reasons; or
- because of concerns about adverse effects, possible misuse, overuse or abuse.[21]

3.5 A restriction may simply specify the therapeutic use for which the drug may be used, or it may contain directions about drug or medical procedures that must be completed prior to prescription, and/or about the patient group. For example, the restriction for Olanzapine is: 'Schizophrenia; maintenance treatment of bipolar I disorder'.[22] In contrast, the restriction for Clopidogrel is more complex and includes direction about the specified conditions and the patient's pharmacological history. Restrictions may also be specific about what stage a condition must reach before the drug can be prescribed. For example, the restriction for Alendronate, states, *inter alia*, that the drug can only be prescribed for the 'treatment for established osteoporosis in patients with fracture due to minimal trauma'.[23]

3.6 Restrictions may be suggested by the drug's sponsor in its submission or by Health's secretariats and committees when considering a submission. More complex or contentious restrictions are considered by the Restrictions Working Group (RWG), which is comprised of Health and Medicare Australia personnel. While the RWG does not have terms of reference, Health informed the ANAO that its purpose is to provide advice to the Pharmaceutical Benefits Advisory Committee (PBAC) on the practicality, appropriateness and wording of restrictions. The RWG meets twice for each PBAC meeting:

- prior to the PBAC meeting, but following the Economics Sub-Committee (ESC) and Drug Utilisation Sub-Committee (DUSC) meetings, to consider the proposed restriction; and
- following the PBAC meeting to finalise the wording of the restriction in light of the PBAC's discussions.

3.7 Proposed restrictions that are complex and likely to be controversial are also discussed with relevant specialist groups. For example, a recommended restriction for a new cancer drug may be discussed with oncology specialists.

---

[21] Department of Health and Ageing, September 2002, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC*, Health, p.5.

[22] Department of Health and Ageing, December 2005, *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners*, Health, p.270.

[23] Department of Health and Ageing, December 2005, *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners*, Health, p.245.

3.8 In general, restrictions are tighter when a drug is first listed, then relaxed, or conditions are added over time. For example, Olanzapine was originally listed on the PBS in 1997 for schizophrenia and related psychosis where other antipsychotic therapy failed or was inappropriate. In July 2004, following two submissions to the PBAC from the sponsor[24], the listing was broadened to include maintenance treatment of bipolar I disorder. Often when a restriction is loosened or discontinued (which may lead to a larger market for the drug and, potentially, higher profits for the sponsors), Health negotiates a price reduction with the sponsor. For example, when the listing for Latanoprost was changed from restricted to unrestricted in 2000, the level of subsidy paid to the sponsor decreased by fifteen per cent, in two stages, from February 2001.

3.9 Of note is that the length and complexity of restrictions is increasing. The average number of words in restrictions has grown over the past five years, from 19 words in 2000 to 354 words in 2005. However, the ANAO notes that this average is amplified by very lengthy restrictions on a few drugs. For example, one of the drugs in the ANAO's sample, Etanercept, has a 10 614 word restriction on 24 pages of the December 2005 Schedule. Meanwhile, the proportion of restricted items has increased from 50.7 per cent in 2000 to 58.5 per cent in 2005.

3.10 Figure 3.3 shows the number of therapeutic uses and the word length of restrictions for eight drugs in the ANAO's sample when they were first listed and in the December 2005 Schedule.

[24] The PBAC accepted a minor submission from the sponsor following deferral of a major submission in March 2004.

Figure 3.3

Restrictions for the drugs in the ANAO's sample

Drug	When listed		December 2005	
	No. of therapeutic uses	*No. of words in restriction*	*No. of indications*[25]	*No. of words in therapeutic uses*
Alendronate	1	9	3	124
Atorvastatin	1	399	1	337
Clopidogrel	1	119	1	134
Etanercept	1	915	3	10 614
Imatinib	2	290	6	2 096
Latanoprost	1	28	2	0
Olanzapine	1	10	2	7
Tiotropium	1	16	1	15

Note 1: These drugs were first listed between 1996 and 2003.

Note 2: The restriction word count includes any relevant notes to the Schedule and, for Atorvastatin, the General Statement for Lipid-Lowering Drugs.

Source: ANAO analysis.

3.11 Ambiguity of the wording used in the restriction reduces its effectiveness. Medicare Australia reported to the ANAO that ambiguous wording renders restrictions more difficult to enforce. For example, it is difficult for Medicare Australia to monitor and compel compliance with restrictions that contain ambiguous words or phrases such as 'typically'[26], or differentiate between 'treatment' and 'maintenance'.

3.12 The effectiveness of restrictions is also influenced by prescriber intent. A prescriber may believe that prescribing a particular drug is in the best interests of their patient, regardless of the PBS restriction. Prescriber intent may also be influenced by sponsor advertising and professional publications. However, under the *National Health Act 1953* it is an offence for a medical professional to prescribe a subsidised PBS drug outside its restriction. The Act states that:

---

[25] Health defines a new indication as a change in a PBS restriction based on a major submission to the PBAC initiated by the sponsor.

[26] The General Statement for Lipid-lowering Drugs in the Schedule includes the question: 'Has the patient received dietary therapy (typically for 6 weeks)?' (Department of Health and Ageing, December 2005, *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners*, Health, pp.127-128).

> A person shall not by means of impersonation, a false or misleading statement or a fraudulent device, obtain, or by any of those means aid or abet another person to obtain, a pharmaceutical benefit or a payment in respect of the supply of a pharmaceutical benefit.[27]

3.13 In 2003, Medicare Australia commissioned research about prescriber behaviour. The study used qualitative and quantitive research methods to understand prescribers' attitudes, beliefs and motivations. The relevant findings are listed in Figure 3.4.

Figure 3.4

Medicare Australia research—prescriber responses

48 per cent were not aware that prescribing outside the restrictions was breaking the law[28]
40 per cent agreed or strongly agreed, and a further 19 per cent neither agreed nor disagreed, that prescribing outside the restriction was against the law but everyone does it[29]
50 per cent agreed or strongly agreed, and a further 7 per cent neither agreed nor disagreed, that the restricted benefits system was more like a set of guidelines than hard and fast rules
15 percent perceived that prescriptions were written outside restrictions, but only 4 per cent reported doing so
70 per cent were not aware of the PBAC's role in setting restrictions
91 per cent felt that the setting of restrictions was handled well
74 per cent agreed or strongly agreed, and a further 10 per cent neither agreed nor disagreed, that without the restrictions the PBS would be unaffordable
51 per cent agreed or strongly agreed that criteria for prescribing restricted benefit items often did not reflect the best clinical practice, but 33 per cent disagreed or strongly disagreed

Source: *PBS Restrictions Final Report*, prepared for the Health Insurance Commission, July 2003.

---

[27] Offences against Part VII of the *National Health Act 1953*, which relates to pharmaceutical benefits, are described in section 103.

[28] It is not clear from the report of the research findings if it was explained to prescribers that this question applied to PBS items for which a subsidy was paid. It is not illegal to prescribe drugs outside the restriction, but it is illegal to prescribe PBS drugs, for which a subsidy is paid, outside restrictions. For example, Alendronate is listed on the PBS for osteoporosis, subject to certain conditions including that patients must have had a fracture due to minimal trauma. While it is permissible to prescribe Alendronate to patients who have not suffered a fracture, this prescription must be fully paid by the patient, and not subsidised through the PBS.

[29] ibid.

3.14 In summary, the research found that while prescribers recognised the need to restrict PBS benefits, restrictions were considered by prescribers to be guidelines only and prescribing outside restrictions was not uncommon. The findings of a more limited 2004 qualitative survey of prescribers were similar. The 2004 survey, commissioned by Medicare Australia, found that respondents accepted prescribing outside restrictions as the norm.

Reviewing restrictions

3.15 In 2004–05, the restrictions on 150 listed drugs were changed. The majority of these changes were made as the result of a submission from a sponsor requesting a minor alteration to a restriction, maximum quantity or allowable number of prescription repeats. Changes to restrictions may also be made in the absence of a sponsor's submission. In the four meetings between June 2004 and July 2005, the PBAC recommended changes to the wording of 61 restrictions. Of these, 49 changes were a result of requests not originating from sponsors. The majority of these requests came from Medicare Australia (29), and stakeholder groups (19). Only one change originated from Health or a committee secretariat—the PBAC Secretariat suggested a minor change to the PBAC's recommended wording of the restriction of a listed drug.

3.16 Until late 1999, the PBAC secretariat reviewed restrictions, focussing on quantities by therapeutic group, for example the maximum quantity of tablets that could be prescribed per month. These reviews were not considered by Health or the PBAC to be useful as they did not examine the relevance or appropriateness of restrictions. Recently, the PBAC requested that the PBAC secretariat, with the assistance of the RWG, recommence reviewing restrictions to ensure they are relevant and appropriate. However, to date no action has been taken on these reviews.

3.17 The ANAO proposes that, to ensure restrictions are current and appropriate, Health assess the costs and benefits of systematically reviewing all restrictions on drugs currently listed on the PBS and, if favourable, develop and implement a programme of review. This programme, to be implemented by the RWG, should include a timetable for review and response, reporting processes and options for follow-up action.

3.18 Medicare Australia also reviewed the wording of some restrictions, including all authority required restrictions, in 2003. Medicare Australia informed the ANAO that the purpose of the review was to clarify the wording of restrictions and ensure that wording accorded with the intent of the listing.

Authority required restrictions

3.19 A drug with an authority required restriction is similar to a restricted benefit as it can only be prescribed for specific therapeutic uses as described in the PBS Schedule, but it also requires prior approval from Medicare Australia. The Schedule specifies whether Medicare Australia will grant this approval by telephone or in writing. Within the ANAO's sample of drugs, five require prior approval to prescribe:

- three by telephone – Alendronate, Clopidogrel and Olanzapine; and
- two in writing – Etanercept and Imatinib.

The Government's subsidy for these five drugs was $470 million in 2004–05.

3.20 In interviews, Health and Medicare Australia personnel and stakeholders informed the ANAO that authority required restrictions, particularly those requiring a written authority, were generally believed to be a more effective means of controlling prescribing of high cost drugs than general restrictions.

3.21 However, prescribers know what questions they will be asked through the telephone authority system to obtain approval.[30] In interviews with the ANAO, Health and Medicare Australia personnel stated that it is possible for prescribers to answer the questions in such a way that approval is likely. For example, a psychiatrist who prescribes Olanzapine to treat a patient with bipolar I disorder must ring Medicare Australia for approval. As it is highly likely that such a specialist has prescribed Olanzapine in the past and is familiar with the restrictions on its prescribing, they will know how to respond to the questions they are asked. Other prescribers may consider the system too time-consuming or complex, and therefore they prescribe other drugs which do not require Medicare Australia's approval. This may result in patients receiving sub-optimal medication or the patients most in need of the drugs not receiving them.

3.22 Medicare Australia trialled an online authority prescription system (the Authority Notification System) in 2000. This trial enabled heath professionals to authorise their own authority required restrictions. The focus of this trial was on testing the technical feasibility of an online authority system. The

[30] Questions related to authority required restrictions are listed on Medicare Australia's website at <www.medicareaustralia.com.au>.

ANAO noted that during the trial, prescribing levels of authority prescribed drugs increased by 39 per cent.

3.23 Only a minority of the drugs listed on the Schedule require authority prior to prescribing. Currently, 412 PBS items require a telephone authority and 14 required a written authority. As with drugs with restrictions, to exercise greater control of prescribing of PBS drugs, the PBAC is recommending that an increasing number of drugs be subject to authority required restrictions. In the past five years the number of items requiring an authority has risen from 20.1 per cent (285 items) of total items in June 2000 to 27 per cent in December 2005.

3.24 Health and Medicare Australia personnel informed the ANAO that authority required restrictions are only employed if the number of prescriptions is expected to be low. If an authority required restriction was placed on a drug that is expected to be widely prescribed, even if it is also likely to be of high cost to the PBS, the number of telephone calls would render it impractical for Medicare Australia to implement. The same applies to written authorities, where large volumes would result in delays in patients receiving drugs. Therefore, while some authorities may be adopted for clinical reasons, authorities are usually only required for drugs that have small treatment populations and are costly to the PBS.

3.25 Paradoxically, the drugs with small treatment populations are those that are least likely to be prescribed outside the restriction and, therefore, are least likely to require prior authority. For example, the clinical use and treatment population for Imatinib is very limited, but the drug has a complex restriction requiring a written authority. Nevertheless, the ANAO acknowledges that authority required restrictions are considered to be effective in controlling use outside subsidy conditions.

Risk sharing agreements

3.26 An RSA is an agreement between Health and a sponsor to share the risk of a drug costing the PBS more than estimated. RSAs are generally applied to drugs that are expected to be costly to the Commonwealth. Cabinet encourages Health to consider RSAs for high cost drugs. An RSA may take several forms, including a price volume agreement, depending upon the circumstances of the listing. In simple terms, under the most common RSA the sponsor agrees to rebate to the Commonwealth an agreed percentage of the

subsidy amount paid for any sales in excess of a certain amount, referred to as a cap. Figure 3.5 shows some hypothetical examples of different types of RSAs.

Figure 3.5

Hypothetical examples of RSAs between the Government and drug sponsors

Drugs	Terms of the RSA
A	Rebate of 25% of cost to the PBS plus 2 x 2.5% price decreases if sales reach: Year 1: $120 million Year 2: $130 million Year 3: $140 million Year 4: $150 million
B	Rebate of: 10% of sales in excess of $28 million 15% of sales in excess of $38 million 20% of sales in excess of $48 million
C (RSA 1)	Rebate of $158 per unit for sales over $5 million
C (RSA 2)	Rebate of 75% of cost to the PBS over $55 million

Source: ANAO analysis of Health data.

3.27 The first formal RSA between Health and a sponsor company was signed in October 2003. Prior to this, pricing arrangements ratified through an exchange of letters between Health and the sponsor company were sometimes used for high cost drugs, for drugs that were at a high risk of being used outside subsidy conditions and/or for drugs where usage may be greater than estimated. These arrangements were most commonly price volume arrangements whereby the sponsor agreed to lower the price of a drug once a certain volume of sales was reached.

3.28 Health is increasingly using RSAs. Between October 2003 and November 2005, 14 RSAs were signed and, as at November 2005, Health was negotiating a further nine.

3.29 Health negotiated an agreement for one other drug in the ANAO's sample. Health was concerned that there was a high risk that this drug would be used to treat a condition for which it was not subsidised. Under the agreement the sponsor would rebate to the Commonwealth any subsidy paid for prescribing for the unsubsidised condition if that condition represented greater than 10 per cent of total prescribing. The sponsor, after consultation with Health, commissioned an audit of prescribing patterns. The sponsor's audit was completed in 2004 and found that prescribing was within the

10 per cent allowed by the agreement. Health accepted the findings of this audit and, as such, the agreement is now void.

3.30 Health informed the ANAO that RSAs are generally negotiated with sponsors for high cost drugs when there is a high risk that the drug will be prescribed outside subsidy condition, or when there is uncertainty about estimated usage (and consequent cost to the PBS). However, the focus of an RSA is on providing more certainty regarding PBS expenditure on particular drugs and containing Government expenditure. If a drug reaches usage caps in an RSA, this does not necessarily mean that use is inappropriate or outside subsidy conditions. Therefore, an RSA does not prevent a drug being used outside subsidy conditions.

3.31 Some early RSAs were negotiated on the basis of a 'worst-case scenario', whereby caps were based on the highest expected volume of sales. Health recognised that under this approach it was unlikely that the caps would be reached, and that the risk to the sponsor was minimal at best and, therefore, the arrangements were not true 'risk sharing' agreements. For example, in the hypothetical examples in Figure 3.5, there is a negotiated cap of $55 million per year for Drug C (RSA2). However, if actual sales of Drug C reached only $13.8 million in the first year of listing, which is 75 per cent under the cap, the RSA would not be activated.

3.32 Health's approach to negotiating RSAs has improved over time. A more realistic approach has now been adopted whereby RSAs are negotiated on the basis of likely expected usage, as estimated during the submission and listing process and confirmed or revised following consideration by DUSC and PBAC. Nevertheless, as demonstrated in Figure 3.6, Health does not expect the caps of the majority of RSAs to be reached in the current year.[31] On average, PBS prescriptions written for drugs with RSAs are projected to reach only 64 per cent of the caps in the current year. To November 2005, two RSAs have been activated resulting in rebates from three sponsors and a further three RSAs will be activated in the current year.

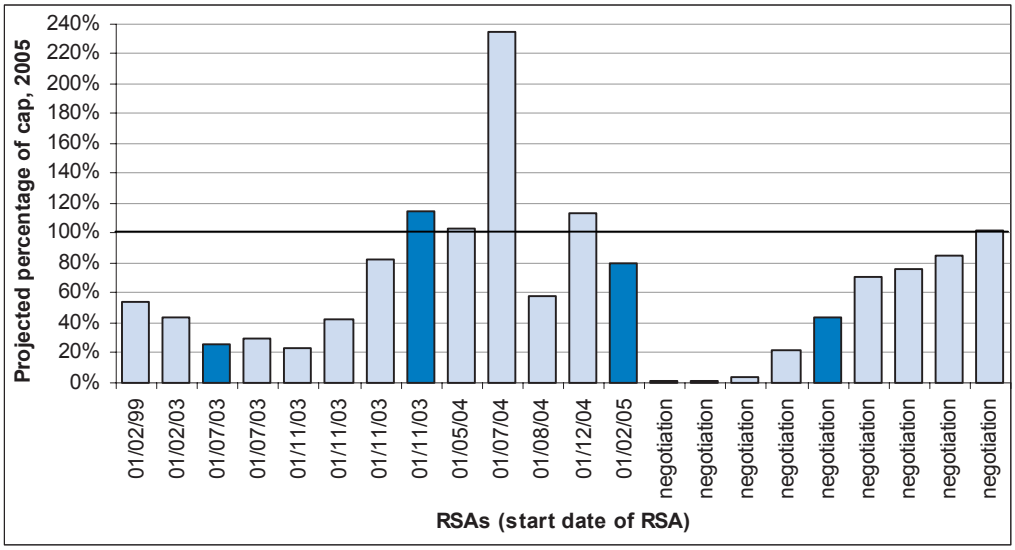
---

[31] Health records, and calculates projections for, RSAs according to the anniversary of their signing, not by calendar or financial year. For example, for the projections discussed in this section:

- for an RSA signed on 1 February, the projections would cover the period 1 February 2005 to 31 January 2006; and
- for an RSA signed on 1 November, the projections would cover the period 1 November 2005 to 31 October 2006.

Figure 3.6

Projected percentage of RSA caps to be reached in the current year



Note 1: Negotiation refers to those RSAs Health was negotiating with sponsors as at 28 November 2005.

Note 2: One RSA has two caps (dollar and script); the script cap has been excluded from the graph to ensure the RSA is recorded once only.

Note 3: Dark blue bars represent drugs in the ANAO's sample.

Note 4: Projection calculated based on data to 28 November 2005.

Source: ANAO analysis of Health data.

3.33 One of the difficulties of negotiating RSAs is anticipating the impact of new drugs on the market. For example, if an RSA is negotiated with a sponsor for a drug, and during the period of the RSA a new drug becomes available for the same therapeutic use, the market share of the original drug is likely to decrease. One approach used by Health to overcome this problem is to negotiate individual or combined RSAs that incorporate market shares. Currently, two RSAs use this approach. For example, for one of these RSAs, one drug has two sponsors. When PBS prescriptions for this drug reach a cap of $10 million, reimbursement to the Commonwealth will be calculated based on each companies market share of that drug.

3.34 Two RSAs will expire in 2006. Health informed the ANAO that it will review the effectiveness of these two RSAs prior to expiry, and that it will review each RSA prior to expiry to determine whether ongoing arrangements are required.

Selecting the measure

3.35 The type of measure to be applied to a drug is discussed by Health's expert committees and negotiated between Health and the sponsor of the drug. While Health encourages sponsors to propose one or more measures as part of a submission, a specific measure may be suggested by any of the parties involved in the process and at any stage. The selection of a measure may be guided by practice or practicality, as illustrated in Figure 3.7.

Figure 3.7

General practice when selecting a measure

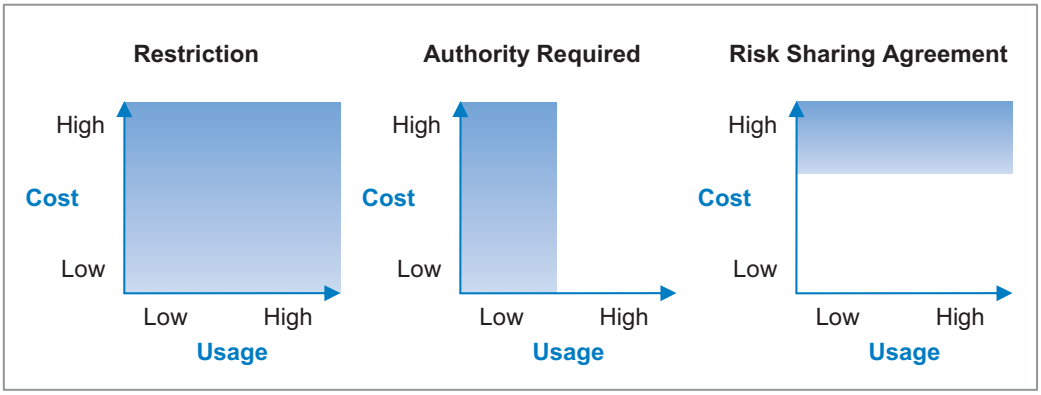
Measure	Criteria	Practice
Restrictions	No	▪ generally used more commonly than other measures
Authority required restrictions	No	▪ generally used if the number of prescriptions is expected to be low
Risk sharing agreement	No	▪ generally used for particularly high cost drugs ▪ Cabinet encourages Health to consider negotiating agreements with sponsors of particularly high cost drugs to share the risk of a drug costing more than estimated

Source: ANAO.

3.36 As Figure 3.8 demonstrates, authority required restrictions and RSAs tend to be used for drugs that are of high cost to the PBS, while restrictions not requiring an authority tend to be applied more broadly.

Figure 3.8

Measures used to decrease the risk of PBS drugs being used outside subsidy conditions



Note: This figure is based on ANAO observations and is for illustrative purposes only.

Source: ANAO.

3.37 Health does not have specific criteria to inform its selection of which measure to adopt under particular circumstances or for which drugs or groups of drugs. In developing such criteria, Health could capture, document and use its extensive knowledge of the pharmaceutical industry and the PBS listing process. Criteria to guide the selection of measures would enhance consistency across drugs and therapeutic groups, so that all drugs in a specific therapeutic group would be subject to the same measures. For example, if a new statin was listed on the PBS it would be subject to the same conditions as other statins, such as Atorvastatin. Such an approach to selecting measures would also be more efficient and objective than the current ad hoc approach, and may reduce the pressure of the negotiation process between Health and drug sponsors.

3.38 When considering listing, Health and the PBAC tend to consider why a drug should be subject to a particular measure, rather than why a drug should not. There are a few reasons why Health and the PBAC adopt a measure, including that: there is a high risk that the drug will be used outside subsidy conditions; or the drug is expected to be costly to the PBS. Some of the reasons why a measure may not be adopted include:

- the risk of use outside subsidy conditions is low;
- the drug is expected to be of low cost to the PBS; and
- the drug is cost-effective for a wide number of therapeutic uses.

Periodically reviewing the measures

3.39 In general, Health is increasingly using the three measures discussed in this Chapter to control the use of PBS drugs. As mentioned above, the number of RSAs has increased since their inception in 2003, with nine currently being negotiated. The length of restrictions has also increased, as has the number of items with restrictions and requiring prior authority.

3.40 The extent to which Health assesses these measures would be improved by a review of what impact each type of measure has had on the use of drugs outside subsidy conditions; or the contribution that the measure(s) has made to containing Commonwealth expenditure or slowing the PBS expenditure growth rate. This type of review would enable Health to have information on whether the measures are:

- effective in containing PBS prescribing to within PBS subsidy conditions, and thereby controlling expenditure;
- have had no impact on PBS cost or use outside PBS subsidy conditions; or
- have resulted in underutilisation of some drugs.

For this reason, the ANAO has proposed that Health periodically review the utility of these measures.

Recommendation No.1

3.41 The ANAO recommends that Health:

- develop and implement criteria to guide its selection of measures to control the use of drugs when listing or altering the listing conditions of existing drugs on the Pharmaceutical Benefits Scheme; and
- periodically review the success of these measures.

Health's response

3.42 The Department agrees with this recommendation. The Department supports the findings of the audit while noting the importance of a sufficiently flexible approach to guidelines for the selection of risk management measures. A guidelines approach will improve transparency and aid decision making, provided that it is not too rigid to embrace new strategies, appropriate to the particular new drugs seeking PBS listing.

4. Estimating Usage and Cost

This chapter analyses how the Department of Health and Ageing reviews drug usage and cost estimates, and examines data issues that impact on the accuracy of those estimates.

Sponsor's estimates

4.1 When a drug's sponsor wishes to list a new drug on the Pharmaceutical Benefits Scheme (PBS), or significantly change the listing of a drug, it makes a major submission to the Pharmaceutical Benefits Advisory Committee (PBAC). Submissions usually include four year estimates of usage and cost to the PBS.[32] The eight drugs in the ANAO's sample have been the subject of 53 submissions since they were listed, as shown in Figure 4.1.

Figure 4.1

Sponsor's submissions since listing

Drug	Date listed	No. of submissions
Alendronate	1 November 1996	12
Atorvastatin	1 February 1998	3
Clopidogrel	1 November 1999	2
Etanercept	1 July 2003	11
Imatinib	1 December 2001	15
Latanoprost	1 May 1998	3
Olanzapine	1 August 1997	5
Tiotropium	1 February 2003	2

Source: Health data.

4.2 Generally, the Department of Health and Ageing (Health) does not develop usage and financial risk profiles for groups of drugs. Instead, it examines sponsors' estimates of usage and cost to the PBS for individual drugs during initial listing and any subsequent change to listing. When considering these estimates, Health considers the risk of use outside subsidy condition.

[32] The *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC* require that sponsors include estimates for two years. Health has informed the ANAO that the request to provide four year estimates is widely understood by applicants. The ANAO encourages Health to clarify this discrepancy between practice and the written guidelines.

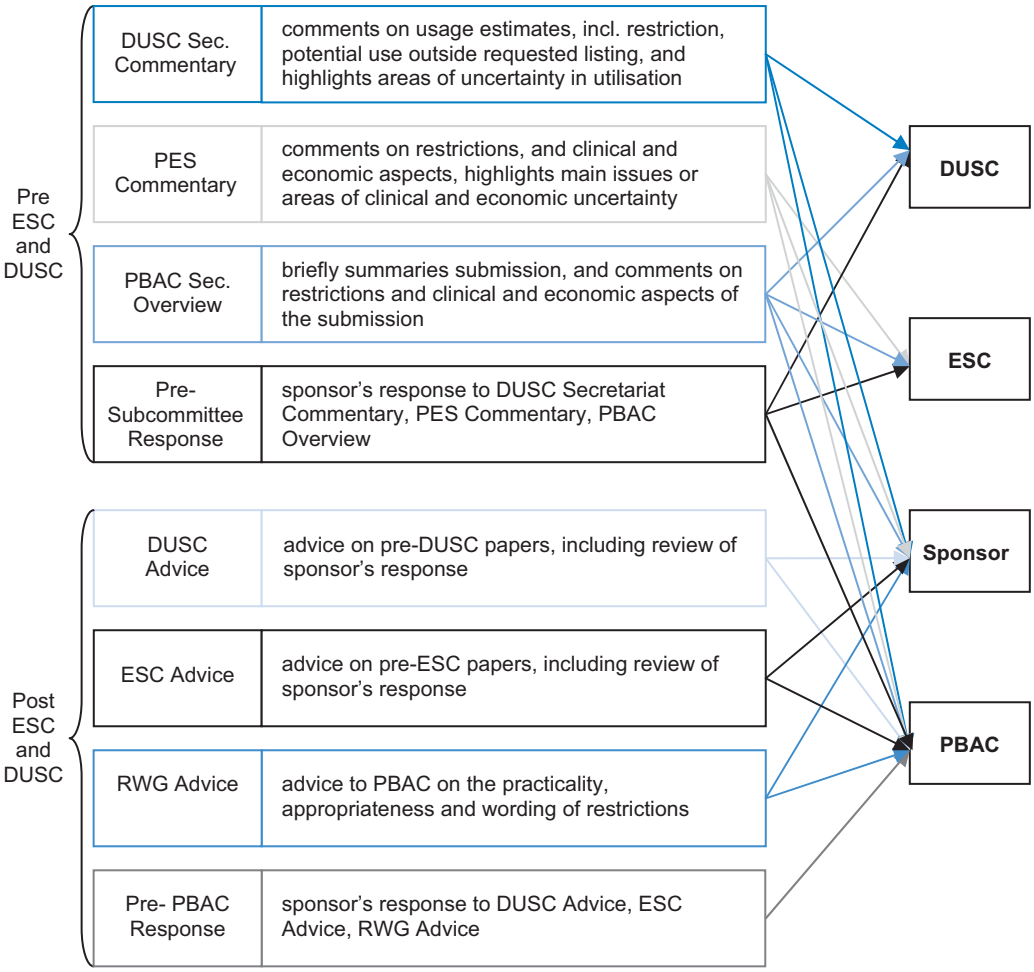
4.3 Health provides *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC* (Guidelines) to sponsors on how to develop a submission for listing a new drug or changing the listing condition of an existing drug. These Guidelines include instructions on how to estimate usage and cost. Sponsors also have the option of meeting with Health prior to making a submission to the PBAC. The purpose of these discussions is to provide the sponsor with an opportunity to seek advice about matters covered by its submission.

Evaluating estimates

4.4 Following receipt of a submission, Health and its PBS committees evaluate the sponsor's submission. This evaluation includes a review of the sponsor's estimates. The committees do not separately estimate drug usage and cost. The expert committees and their respective secretariats evaluate the estimates at a number of stages in the process. At each stage, the committee secretariats produce a paper (commentary or advice) to assist committee members to understand the submission and to highlight areas of uncertainty. This review process is complex, as illustrated by Figure 4.2.

Figure 4.2

Reviewing submissions



Note: The PES is the Pharmaceutical Evaluation Section of Health, which includes the ESC and DUSC Secretariats.

Source: ANAO analysis.

4.5 The Drug Utilisation Sub-Committee (DUSC) has the primary responsibility for evaluating sponsors' usage estimates. However, DUSC does not review every submission; it reviews a selection of major submissions. The DUSC secretariat has developed criteria that guide the choice of major submissions it will examine.

4.6 Major submissions not reviewed by DUSC include those:

- previously reviewed by DUSC as the result of a prior submission that has not changed substantially or that includes changes that conform with previous DUSC Advice;
- where the patient group is defined, that is, where the treatment population is known; or
- where the market is considered stable.

4.7 In contrast, the Economics Sub-Committee (ESC) reviews every major submission. This is because PBAC recommendations to list a drug must take into account the comparative costs and benefits of the drug, and ESC is the sub-committee responsible for reviewing economic aspects of a submission, including the drug's cost-effectiveness.

4.8 The secretariats have developed standard templates, which reflect the format of the submissions, to review the latter. For example, using the standard template, 'DUSC Secretariat Commentary', the DUSC secretariat checks the assumptions and clinical data, accuracy of the calculations, sources of information, impact on the market and other relevant drugs and therapies, and potential for the drug to be prescribed for therapeutic uses other than those in the submission.

4.9 Committee members are also assigned to review submissions. For DUSC reviews, two members are assigned as first and second 'discussants' to review the submission. The discussants are assigned based on specialty or interest. The discussant's role is to lead the discussion about usage for that drug at the next DUSC meeting. The discussants are provided with guidance that outlines the areas the discussant is to focus on when critically reviewing the data in the submission. These areas include consideration of:

- whether the usage estimates are reasonable;
- whether there is an identifiable reason why usage estimates are not considered to be reasonable;
- additional information needed to increase confidence; and
- level of confidence placed on the estimates.

4.10 Following the DUSC meeting, DUSC reports to the PBAC (DUSC Advice), advising on:

- commentary about the submission's usage estimates including, if applicable, the reasons for any disagreement with those estimates;
- commentary about potential for use of the drug outside the requested therapeutic uses and restrictions or beyond expectations; and
- a recommendation about the submission.

4.11 To encourage communication, each committee has at least one member who is a member of another committee. For example, three members of PBAC are members of DUSC and another three are members of ESC. Representatives from each of the secretariats also attend each of the meetings. For example, DUSC secretariat staff attend the PBAC and ESC meetings.

4.12 In July/August 2003 and December 2004/January 2005 DUSC, with Medicines Australia[33], surveyed sponsors who had their submissions reviewed by DUSC for specified PBAC meetings. The survey asked about the DUSC Secretariat Commentary and DUSC Advice to the PBAC. Seventeen sponsors, relating to 26 submissions, replied, which was a 61 per cent response rate. In general, the results of the survey were positive and showed an improvement from a similar 2003 survey. Negative responses usually reflected disagreements between the sponsor and the secretariat about the results of DUSC's review of the sponsor's submission.

4.13 In summary, usage estimates are the result of an iterative process wherein the sponsor submits its original estimates, these are evaluated by several committee secretariats and expert committees, and the sponsor is given the opportunity to comment on the evaluations.

4.14 Health's objective in reviewing estimates is to ensure that they are as accurate as the available data and information allow. The ANAO found that the submission reviews were robust, and that Health assured itself that the information in the submissions that formed the basis of estimates was the most relevant available and that calculations were accurate. For example, Health checked the accuracy of calculations in the submissions and when evaluating the epidemiological data provided by the sponsor, carried out independent searches of relevant data, sometimes identifying limitations in data or omissions of relevant data and sources. In addition, the discussions during the

[33] Medicines Australia is the peak body representing the prescription medicines industry in Australia.

committee meetings observed by the ANAO appeared to be full and robust reviews of any problems or issues with the submissions. Therefore, Health's processes to review sponsors' estimates in submissions and to inform its own judgments were reasonable.

Accuracy of estimates

4.15 Cost and usage estimates can only be as accurate as the data used in the calculations. Health, its committees, and the industry all informed the ANAO that it is difficult to accurately estimate drug usage in a submission. Some of the issues associated with data accuracy, availability and reliability prior to listing a drug include:

- lack of epidemiological data, particularly with previously untreated or rare conditions;
- small clinical trials (for example, with small patient numbers) resulting in limited data and difficulties with extrapolating the findings to a wider patient group;
- relevance of international clinical trials;
- applicability of broader epidemiological data when the intended treatment group is limited by restrictions;
- difficulty of measuring unmet clinical need;
- difficulty of estimating incidence of disease, and the proportion of patients that meet restriction criteria; and
- difficulty of determining and verifying market share.

4.16 In the absence of definitive data and estimates, the PBAC takes a risk management approach when deciding whether to recommend the listing of PBS drugs. That is, Health and the PBAC must find a balance between:

- recommending listing to meet clinical need based on incomplete data, but with the assurance that it has accessed and evaluated the best information available; and
- delaying listing until more conclusive information is available.

4.17 A consequence of the former approach is that the actual usage and cost to the PBS of specific drugs may be different from the estimates made prior to listing. This issue is discussed further in Chapter 5.

5. Monitoring Usage and Cost

This chapter assesses how the Department of Health and Ageing monitors selected Pharmaceutical Benefits Scheme drugs and investigates differences between estimated and actual drug usage and cost. The Chapter also describes Medicare Australia's role in administering prescriber compliance with the conditions of Pharmaceutical Benefits Scheme listing.

Monitoring PBS drugs

5.1 The Department of Health and Ageing's (Health's) monitoring of Pharmaceutical Benefits Scheme (PBS) drug usage and cost is generally limited to monitoring those drugs with a risk sharing agreement (RSA). During this process, Health tracks actual usage and expenditure against estimated usage and expenditure for an individual drug, as per the terms of the RSA. Health does not conduct any investigation of discrepancies identified during this monitoring. Health investigates drug usage for a small number of drugs through the Predicted Versus Actual Systematic Review (PvA). These processes are discussed in more detail below.

Monitoring risk sharing agreements

5.2 Health receives monthly data from Medicare Australia for each drug with an RSA.[34] Health uses this data to track actual usage and expenditure against the usage and expenditure amount agreed in each RSA. Health also receives quarterly data from the States and Territories about drugs that are prescribed in public hospitals under the section 100 Highly Specialised Drugs Program.[35]

5.3 Prior to the ANAO's audit, Health monitored RSAs using a basic spreadsheet that included basic details of the drug and the RSA cap for that year. Health has since improved this analysis and monitoring, which now includes the following fields :

- RSA information;

[34] This data is limited to those PBS listed drugs with an RSA that are prescribed outside public hospitals.

[35] Section 100 of the *National Health Act 1953* enables provision of a pharmaceutical benefit in circumstances where the usual PBS supply arrangements are unsuitable. For example, due to the specific clinical use or other special features, the initial prescribing of a highly specialised drug is usually restricted to being in hospitals that have access to appropriate specialist facilities. Highly specialised drugs are among those supplied via section 100.

- where the drug is within the agreement (for example, the drug is in the second year of a four year agreement);
- the stage in the year (for example, the drug is in the second month of year two);
- the agreed volume limit (for example, the agreed maximum usage of that drug);
- the total volume to date for the year (for example, the total volume as a percentage of 12 months usage); and
- a projection of usage over 12 months (for example, a forward estimate so that Health can predict whether the drug will be over or under the agreed amount).

5.4 The results of RSA monitoring are a permanent agenda item at Pharmaceutical Benefits Pricing Authority (PBPA) meetings. In this way Health ensures that the PBPA members are fully informed regarding the use of drugs with RSAs.

5.5 The first two RSAs will end in 2006. In November 2005 Health initiated plans to review these RSAs. Health informed the ANAO that this review will consider the effectiveness of the two RSAs, whether each RSA has met its objective, and what, if any, issues arose during the life of the RSA.

Analysing drug usage

5.6 As a sub-committee of the PBAC, one of the tasks undertaken by the Drug Utilisation Sub-Committee (DUSC) is the post-listing analysis of some PBS drugs. Since the mid-1990s, the PvA has become an increasingly important function of DUSC, and the PvA process was formalised in 2003. In addition, DUSC can conduct reviews of specific drugs, often at the request of the PBAC. Health informed the ANAO that while this type of review does occur, it is ad hoc.

5.7 Health's PvA procedures state that DUSC conducts PvAs 12 months after listing, and again at 24 months after listing, if required, on all new drugs and on those drugs with major changes. An example of a major change is when a listing is changed from restricted to unrestricted. The PBAC may also request that DUSC review a drug. For example, the PBAC can write to DUSC and request a PvA to review the effects of a change it has recommended. The ANAO was informed that these requests are not made often, and that it would

be too time consuming for DUSC to review each decision or change made by the PBAC.

5.8 Health's procedures state that PvAs must be conducted on all new drugs 12 months after listing, and again at 24 months after listing, if required. In January 2006, Health informed the ANAO that in 2003–04 there were 19 new drugs listed on the PBS. Of these 19 new drugs, 12 were subject to a PvA and a further five were scheduled for review in 2006. PvAs had not been scheduled for the remaining two drugs listed in 2003–04. Therefore, in not completing PvAs as specified, Health is not conducting timely analysis on the use of all new drugs listed on the PBS.

Conducting a Predicted Versus Actual Systematic Analysis

5.9 During a PvA, DUSC reviews the information established during pre-listing, and conducts additional analysis to compare the predicted usage and expenditure to the actual usage and expenditure. This analysis is the only systematic investigation on the use and expenditure of PBS drugs currently conducted by Health.

5.10 The DUSC Secretariat developed a format for conducting PvAs. This was last revised in March 2005, and lists the analysis that should be conducted by DUSC during the PvA. For example, in summarising the main points of the PvA, Health's standard approach suggests that DUSC should ask whether there is a divergence from the estimates provided in the submission, the direction of any divergence, what factors may have contributed to this, and whether there are implications for similar submissions.

5.11 For example, when estimated figures do not equal actual figures, this does not necessarily represent prescribing outside PBS subsidy conditions. Health must consider that the estimates may have been incorrect due to incomplete data and/or assumptions provided by the sponsor pre-listing. In this case, the analysis, modelling and/or predictions based on these data and assumptions would also be flawed.

5.12 Other factors that may impact drug usage, which are described in the DUSC procedures, include:

- social, behavioural, economic and policy factors;
- additional drugs listed on the PBS for the same therapeutic use;
- changes in clinical practice;

- uncertainty in sources of data;
- the influence of research on practice or public perception; and
- other uncertainties identified during listing.

5.13 Health accesses various sources of information during the PvA. These sources include anecdotal evidence, specialist groups, hospital evaluations, other data providers and advertising by sponsors. Health uses this information to identify the cause of any difference between estimated and actual usage, and ultimately between estimated and actual cost to the government.

5.14 The ANAO analysed the PvAs conducted on the drugs in its sample. Notwithstanding that, the process and results are indicative of Health's other PvAs. Since 2003, when the PvA process was formalised, DUSC has conducted 12 month PvAs on six of the eight drugs in the ANAO sample, and a 24 month PvA on one. These PvAs are summarised in Figure 5.1.

Figure 5.1

Information in PvAs on ANAO sample since 2003

Drug	Date listed	PvA date	Actual usage (scripts)	Actual expenditure
1. Alendronate (70mg only)	Feb 1997	Nov 2003	May 2001–April 2002 : 759 378 May 2002–April 2003: 1 514 827	Not documented
2. Atorvastatin (80mg only)	Not documented	Nov 2002	Aug 2001–Jul 2002: 135 165[36] Aug 2001–Jul 2002: 5 586 780[37]	Aug 2001–Jul 2002: $14.7 m[36] Aug 2001–Jul 2002: $292.7 m[37]
3. Etanercept[38]	Aug 2003	Jun 2005	Aug 2003–July 2004: 1114 (patients) Aug 2003–Sept 2004: 8901 (scripts)	Aug 2003–Dec 2003: $2.9 m Jan 2004–Sept 2004: $15.0 m
4. Imatinib	Dec 2001	Aug 2003	Yr 1: 1 181[39] Dec 2002–Apr 2003: 1 318[40]	Yr 1: $7.1 m[39] Dec 2002–Apr 2003: $6.3 m[40]
5. Latanoprost	May 1998	Jun 2003	Yr 1: 1 182 272 Yr 2: 1 385 349	Yr 1: $37.3 m Yr 2: $40.6 m
6a. Tiotropium (12 month)	Mar 2002	Oct 2004	Yr 1: 527 661	Yr 1: $39.0 m
6b. Tiotropium (24 month)	Mar 2002	Sep 2005	Yr 2: 932 434	Yr 2: $68.6 m

Source: ANAO analysis.

5.15 Two drugs in the ANAO's sample have not been subject to a PvA since 2003. Both of these were investigated prior to the PvA process being established. While these investigations identified higher than predicted usage of this drug, there was no action or change as a result.

5.16 Three of the seven PvAs conducted on the drugs in the ANAO's sample mentioned factors that may account for variations between estimated and actual usage, but there was little examination or analysis. Of note is that the 24 month PvAs examined by the ANAO, including the PvA on Tiotropium (see Figure 5.1), were more detailed in analysis and investigation than others.

---

[36] Atorvastatin–80mg only.

[37] Atorvastatin–total for 80mg, 40mg, 20mg and 10mg.

[38] Etanercept–items 8637N and 8638P only.

[39] Imatinib–blast and accelerated phases only.

[40] Imatinib–chronic, blast and accelerated phases.

Figure 5.2 shows the analysis required by the DUSC format against the seven PVA results for the drugs in the ANAO sample.

Figure 5.2

PvA results for ANAO sample since 2003

PvA purpose and objective	PvA analysis						
	Alendronate	*Atorvastatin*	*Etanercept*	*Imatinib*	*Latanoprost*	*Tiotropium 12 month*	*Tiotropium 24 month*
Compare expected utilisation with actual utilisation	✗	✗	✓[1]	✓[2]	✓	✓[3]	✓[3]
Examine various factors which might account for variation to the expected utilisation	✓	✗	✓	✗	✗	✗	✓
Provide general insights to improve future predictions	✗	✗	✓	✗	✗	✗	✓
Identify problems with individual drugs that may be referred to PBAC	✗	✗	✓	✗	✗	✗	✗

Legend: ✓ = analysis in PvA complied with PvA purpose and objective.

✗ = analysis in PvA did not comply with PvA purpose and objective.

Notes:
1. Comparison of patient numbers for one year only, in other years comparison was between estimated patient numbers and actual script numbers.
2. Comparison between estimated patient numbers and actual script numbers.
3. Comparison using script numbers only.

Source: ANAO analysis.

5.17 As demonstrated in Figure 5.2, the ANAO compared the results of the seven PvAs with Health's purpose and objective for conducting PvAs. In analysing the PvAs, the ANAO found:

- there was no comparison of predicted usage versus actual usage for every drug;
- there was no comparison of predicted expenditure versus actual expenditure for every drug;
- for one of the drugs, different types of data were used for the comparisons of predicted usage versus actual, that is predicted usage was given in patient numbers, while actual usage was given in script numbers;
- for all drugs there was no significant examination of factors accounting for variations from expected usage. This was either due to a lack of data in the analysis, or a lack of investigation;
- Health did not always provide general insights to improve future predictions; and
- Health did not often refer results to the PBAC for further consideration, despite the fact that the three reviews with the most data analysed showed significant variations between predicted and actual expenditure.

5.18 The ANAO concluded that the PvAs examined were not effective for comparing predicted and actual figures for each drug. For example, for two drugs, the PvAs did not contain data on predictions. For one of these drugs, DUSC noted that 'the likely volume and proportion of use is expected to be small'. In analysing the actual usage and expenditure for this drug through the PvA, DUSC found that there was a 99 per cent increase in usage from year one to year two. For those PvAs that did include comparisons of predicted and actual figures on usage and expenditure, the results of the PvA were not used to inform further action. For example, the PvA for one drug found that the difference between the predicted and the actual cost to the PBS was around 500 per cent, yet there was no documented further action for Health to address this finding.

PVA outcomes

5.19 When DUSC complete a PvA, the results are discussed at the next DUSC meeting. At this time, members determine whether the results are

important, and consider options. These options include providing the information to the PBAC, informing the National Prescribing Service, inviting industry comment, and informing other stakeholders.

5.20 The PBAC can be informed of PvA results in writing, or verbally by the DUSC Secretariat at the PBAC meeting. The PBAC committee members who are DUSC sub-committee members are also aware of the results. Once informed, the PBAC can request a further DUSC review or analysis of a specific question. For example, the PBAC can ask DUSC to establish whether the actual population is different from the submission estimates; whether the restrictions have been difficult to implement; or whether the drug's sponsor is promoting extra use, and whether this use is appropriate or not.

5.21 Health does not often take action as a result of a PvA. For example, for the drugs in the ANAO's sample subject to a PvA since 2003, there was no change to the listing conditions as a result of the PvA process. Following listing, Health affirms that it can only influence existing listing conditions—de-listing a drug in order solely to address a usage or expenditure concern is not a viable option. Once a drug is listed on the PBS and the public has subsidised access, it is very difficult to restrict the terms of that access. Health's position confirms the importance of ensuring that the conditions attached to a drug's listing is appropriate from the time it is first included on the PBS. However, the ANAO proposes that Health further investigate other options, for example:

- building quantifiable measures of the success of restrictions into the wording of the drug's listing;
- listing drugs on a conditional basis, whereby a restriction is set for a specific time, after which it is evaluated for effectiveness and either rejected, approved or changed as a result; and
- requiring sponsors to provide all data relevant to patient use of drugs, including data captured by prescribers through prescribing software.

5.22 If Health conducted PvAs according to its own procedures, a more complete dataset for each drug would result. In turn, this could inform the consideration of options such as conditional listing. While there is no formal process for incorporating results and analysis from the PvA into PBS processes, Health should consider options to do so. In this way the PvA could have a greater impact, particularly when there is a significant difference between predicted and actual usage and expenditure.

5.23 The DUSC Secretariat provides a copy of the PvA results to the drug's sponsor for information or comment. Importantly, the sponsor is not obligated to respond to this process, and Health stated that sponsors rarely respond. During interviews, sponsors stated that they were unsure of Health's expectations at this time. The ANAO proposes that Health consider making sponsor response to the PvA results a condition of listing.

Recommendation No.2

5.24 To maximise the value of the Drug Utilisation Sub-Committee's (DUSC's) predicted versus actual systematic analysis (PvA), the ANAO recommends that Health:

- require that DUSC compare the actual and predicted use of all major drugs and any drugs with significant changes to usage 12 months after listing, and again at 24 months if necessary; and
- ensure DUSC follows Health's procedures for conducting PvAs.

Health's response

5.25 The Department agrees with this recommendation and will develop a strategy for its implementation, working closely with the Drug Utilisation Sub-Committee of the Pharmaceutical Benefits Advisory Committee and with the Advisory Committee itself.

Medicare Australia's compliance role

5.26 The Strategic Partnership Agreement between Health and Medicare Australia contains a schedule that applies to the PBS. Under this schedule, Medicare Australia, rather than Health, is responsible for administering PBS compliance and fraud control activities. In the 2002–03 Federal Budget Medicare Australia was assigned responsibility for a number of initiatives aimed at controlling PBS expenditure. As part of its PBS compliance program, Medicare Australia conducts a PBS Random Compliance Audit and manages a PBS Restrictions Program and an Enhanced Authorities Program.

5.27 Medicare Australia has informed the ANAO that the objective of the PBS Restrictions Program is to reduce prescribing outside PBS restrictions for selected PBS restricted drugs by assisting prescribers to understand and comply with requirements of the *Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practitioners* (Schedule). The selected restricted drugs

included in this program are cox-2 inhibitors, proton pump inhibitors, selective serotonin reuptake inhibitors, anti-asthmatic drugs, and lipid lowering drugs.

5.28 The objective of the Enhanced Authorities Program is to reduce the prescribing of authority prescribed items outside of the PBS restrictions. Medicare Australia has informed the ANAO that through this program, it helps prescribers to better understand and adhere to the restrictions around authority prescribed drugs, which assists with Medicare Australia's monitoring of prescribers' compliance with those restrictions.

5.29 Medicare Australia has a unit responsible for overseeing the approval and use of some specialised and complex drug therapies listed on the PBS. This includes a number of Section 100 Highly Specialised Drugs (HSD). As of June 2004 there were 58 of these drugs listed on the PBS. Medicare Australia is responsible for managing a compliance program in relation to these drugs. Two drugs in the ANAO's sample, Imatinib and Etanercept, are monitored by the specialised drugs unit.

5.30 As discussed in Chapter 1, Health is the focus of this audit. As such, the ANAO did not audit Medicare Australia's role or the programs discussed in this section.

Data used to monitor and investigate drug usage and cost

5.31 Health requires accurate and reliable data to monitor actual usage and expenditure on PBS drugs, and to reconcile this with estimated usage and expenditure. Health receives data from several different sources. The main source is Medicare Australia, supplemented by survey data provided on contract from independent data providers and occasionally provided by specialists, specialist groups and other stakeholders. Health may also commission other data from independent data providers, on occasion, when required.

5.32 The ANAO found the following data issues:

- data on Section 100 HSDs is limited as these drugs are predominantly prescribed in public hospitals. This data limitation includes a lack of discharge and outpatient prescribing data;

- neither Health nor Medicare Australia have data on payments that are below the PBS co-payment amount;[41] and
- when Health needs additional data during analysis (either prior to listing or during the PvA process), this additional data is often not available in a timely way and because Health's data budget is locked into data providing contracts. For example, if DUSC is investigating the treatment population for a specific disease, and does not have access to the necessary data, it could purchase additional data from private sector providers.

5.33 Medicare Australia collects data on PBS prescribing and cost. However Medicare Australia informed the ANAO that it is difficult to link prescribing data to a breach of the relevant legislation[42], as the data on prescribing is not linked to data on diagnosis[43]. Without this data it is difficult to identify whether prescribing is outside PBS subsidy conditions. To link diagnostic data with prescribing data, individual patient records must be examined. Medicare Australia does not have access to this data, and under the privacy provisions of the *National Health Act 1953*[44], this data can not be matched for each patient.

5.34 In interviews, both Health and Medicare Australia stated that without access to a database that links utilisation data with diagnostic data it is not possible to have a full data set on any drug, and therefore it is difficult to implement effective and sound risk management measures. Health stated that excluding Medicare Australia's process of granting prior approval for

---

41 In November 2005, the Fourth Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia was signed. In this agreement, the issue of recording PBS Prescriptions that are priced below the patient co-payment is addressed, with both parties agreeing that, by the end of the Agreement, they will make all reasonable efforts to facilitate the online collection and recording of relevant data on PBS prescriptions that are priced below the patient co-payment. In order to achieve this, the parties agreed that prior to 31 December 2006 they will jointly develop strategies and processes to facilitate the uptake of online collection and recording of under co-payment data.

42 Relevant legislation includes:

- Regulation 19B of the *National Health Act 1953* (Pharmaceutical Benefits Regulations 1960)—Writing a prescription marked PBS/NHS where the medicine should not be supplied as a pharmaceutical benefit;
- Para 103(5) (g) of the *National Health Act 1953*—Aiding and abetting another person to obtain a pharmaceutical benefit or payment for supplying a pharmaceutical benefit by impersonating, making a false or misleading statement or by using a fraudulent device; and
- Section 137.1 of *Criminal Code Act 1995*—Giving false or misleading information to a Commonwealth entity or to a person acting under Commonwealth law where reasonable steps have been taken to notify the person that doing so is a serious offence.

43 The relevant section of the *National Health Act 1953* is Section 103 (5)(g).

44 The relevant section of the *National Health Act 1953* is Section 135AA.

authority-required drugs, restrictions, once in place, are only checked if they are audited by Medicare Australia. In terms of reinforcing those restrictions, Health writes the terms of the restriction in the Schedule, but it has no way of knowing whether the prescriber knows about a restriction at the time of prescribing.

5.35 As such, Health does not have a complete and accurate PBS dataset, which would assist it to monitor the use of PBS drugs and investigate use outside PBS subsidy conditions. Health's contract with its private sector data provider recently ended and Health has requested expressions of interest from data providers. The ANAO supports Health finalising this process as soon as possible.

Improving monitoring processes

5.36 Health's approach to negotiating the terms of RSAs and monitoring RSAs has evolved over time. Health has plans to evaluate two RSAs that are due to end in the near future, and will use the results of this evaluation to analyse what issues, if any, arose during the RSA period. The ANAO expect that Health would use the results of this evaluation to identify areas that did not work, and make adjustments accordingly.

5.37 With respect to PvAs, as discussed in the previous section Health informed the ANAO that it is limited in the actions it can take as a result of a PvA. During the PvA Health reviews any specific concerns noted by any one of the committees before listing. Once inherent uncertainties are accounted for, (for example, Health may determine that a 20 per cent difference is acceptable) if a significant difference between actual and estimated is identified, DUSC can refer the PvA results to the original discussant and committee, to the relevant stakeholder groups, and/or to the drug manufacturer for further consideration. The DUSC Secretariat stated that notwithstanding this referral process, there is limited action available to DUSC at this time, and that the only real opportunity to make changes to a drug's listing condition is to get it right the first time, during the pre-listing process. Paragraph 5.21 discusses the ANAO's suggestions on this issue.

5.38 Since the implementation of the PvA process in 2003, Health has not evaluated the PvA process. Such an evaluation would determine whether the process is effective, and whether it is achieving its purpose and objectives. Other issues with PvAs include that they are predominantly used to analyse

newer submissions from 2003. As such, this process does not include older products.

5.39 Currently there is no formal process for incorporating lessons learned into the various stages of the PBS process. There would be benefits in Health developing processes that ensure that lessons learned are captured and used to inform its decision-making about measures to control the use of PBS drugs not being used according to PBS subsidy conditions. For example, Health could analyse the history of a drug from the date of listing to current usage trends, and use this data to inform and evaluate similar listings.

Ian McPhee
Auditor-General

Canberra ACT
1 June 2006

Appendices

Appendix 1: Contents of Major and Minor Submissions

Major submissions

A major submission is required to:

a. list a new drug on the Schedule of Pharmaceutical Benefits;
b. request a significant change to the listing of a currently restricted drug (including a new indication or a de-restriction);
c. enable a review of the comparative cost-effectiveness of a currently listed drug in order to change a PBAC recommendation to the PBPA on its therapeutic relativity or price premium; or
d. list a new formulation (or strength) of a currently listed drug for which a price premium is requested.

The main body of a major submission is divided into the following four sections and subsections:

Section 1: Details of the proposed drug and its proposed use on the PBS

1.1. Pharmacological class and action
1.2. Indications
1.3. Treatment details
1.4. Co-administered and substituted therapies
1.5. Main comparator
1.6. Differences between the proposed drug and the main comparator

Section 2: Data from comparative randomised trials for main indication

2.1. Description of search strategies for relevant data
2.2. Listing of all comparative randomised trials
2.3. Selection of the comparative randomised trials
2.4. Assessment of the measures taken by investigators to minimise bias in the comparative randomised trials
2.5. Characteristics of the comparative randomised trials
2.6. Analysis of the comparative randomised trials
2.7. Results of the comparative randomised trials
2.8. Interpretation of the results of the comparative randomised trials
2.9. Preliminary economic evaluation based on the evidence from the comparative randomised trials

Section 3: Modelled economic evaluation for main indication

3.1. Need for a modelled evaluation
3.2. Population used in the modelled evaluation

3.3. Approach used in the modelled evaluation
3.4. Variables in the modelled evaluation
3.5. Structure of the modelled evaluation
3.6. Results of the modelled evaluation
3.7. Sensitivity analysis of the modelled evaluation

Section 4: Estimated extent of use and financial implications

4.1. Estimated extent of use of the proposed drug
4.2. Estimated extent of substitution of other drugs
4.3. Estimated financial implications for the PBS
4.4. Estimated financial implications for government health budgets

Minor submissions

A minor submission is required to:

a. list on the Schedule of Pharmaceutical Benefits a new formulation (or strength) of a currently listed drug for which a price premium is not requested, or for which the likely volume and proportion of use is expected to be small (in which case the main aspect of the submission is to justify the clinical need for the product on the PBS);
b. request a change to the maximum quantity per prescription of a currently listed drug;
c. request a change to the number of repeats per prescription of a currently listed drug; or
d. clarify the wording of a restriction (while not altering the intended use).

Depending on the change required, minor submissions may be as simple as a letter explaining or justifying the change and detailing the timing involved or similar to major submission, but without an economic evaluation.

Source: Department of Health and Ageing, September 2002, *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the PBAC*, Health, pp.11 & 23-43.

Appendix 2: Anatomical Therapeutic Chemical Level 1

The following table lists the 14 level one therapeutic groups.

Alimentary tract and metabolism
Blood and blood forming organs
Cardiovascular system
Dermatologicals
Genito urinary system and sex hormones
Systemic hormonal preparations, excluding sex hormones and insulins
Antiinfectives for systemic use
Antineoplastic and immunomodulating agents
Musculo-skeletal system
Nervous system
Antiparasitic products, insecticides and repellents
Respiratory system
Sensory organs
Various

Source: <www1.health.gov.au/pbs/scripts/listtherlvl1.cfm?sched=GA>.

Series Titles

Audit Report No.43 Performance Audit
Assuring Centrelink Payments – The Role of the Random Sample Survey Programme
Department of Family, Community Services and Indigenous Affairs
Department of Employment and Workplace Relations
Department of Education, Science and Training
Centrelink

Audit Report No.42 Performance Audit
Administration of the 30 Per Cent Private Health Insurance Rebate Follow-up Audit
Australian Taxation Office
Department of Health and Ageing
Medicare Australia

Audit Report No.41 Performance Audit
Administration of Primary Care Funding Agreements
Department of Health and Ageing

Audit Report No.40 Performance Audit
Procurement of Explosive Ordnance for the Australian Defence Force (Army)
Department of Defence
Defence Materiel Organisation

Audit Report No.39 Performance Audit
Artbank, Department of Communications, Information Technology and the Arts

Audit Report No.38 Performance Audit
The Australian Research Council's Management of Research Grants

Audit Report No.37 Performance Audit
The Management of Infrastructure, Plant and Equipment

Audit Report No.36 Performance Audit
Management of the Tiger Armed Reconnaissance Helicopter Project–Air 87
Department of Defence
Defence Materiel Organisation

Audit Report No.35 Performance Audit
The Australian Taxation Office's Administration of Activity Statement High Risk Refunds
Australian Taxation Office

Audit Report No.34 Performance Audit
Advance Passenger Processing
Department of Immigration and Multicultural Affairs

Audit Report No.33 Performance Audit
Administration of Petroleum and Tobacco Excise Collections: Follow-up Audit
Australian Taxation Office

Audit Report No.32 Performance Audit
Management of the Tender Process for the Detention Services Contract
Department of Immigration and Multicultural Affairs

Audit Report No.31 Performance Audit
Roads to Recovery
Department of Transport and Regional Services

Audit Report No.30 Performance Audit
The ATO's Strategies to Address the Cash Economy
Australian Taxation Office

Audit Report No.29 Performance Audit
Integrity of Electronic Customer Records
Centrelink

Audit Report No.28 Performance Audit
Management of Net Appropriations

Audit Report No.27 Performance Audit
Reporting of Expenditure on Consultants

Audit Report No.26 Performance Audit
Forms for Individual Service Delivery
Australian Bureau of Statistics
Centrelink
Child Support Agency
Medicare Australia

Audit Report No.25 Performance Audit
ASIC's Implementation of Financial Services Licences

Audit Report No.24 Performance Audit
Acceptance, Maintenance and Support Management of the JORN System
Department of Defence
Defence Materiel Organisation

Audit Report No.23 Protective Security Audit
IT Security Management

Audit Report No.22 Performance Audit
Cross Portfolio Audit of Green Office Procurement

Audit Report No.21 Financial Statement Audit
Audit of the Financial Statements of Australian Government Entities for the Period Ended 30 June 2005

Audit Report No.20 Performance Audit
Regulation of Private Health Insurance by the Private Health Insurance Administration Council
Private Health Insurance Administration Council

Audit Report No.19 Performance Audit
Managing for Quarantine Effectiveness–Follow-up
Department of Agriculture, Fisheries and Forestry
Biosecurity Australia

Audit Report No.18 Performance Audit
Customs Compliance Assurance Strategy for International Cargo
Australian Customs Service

Audit Report No.17 Performance Audit
Administration of the Superannuation Lost Members Register
Australian Taxation Office

Audit Report No.16 Performance Audit
The Management and Processing of Leave

Audit Report No.15 Performance Audit
Administration of the R&D Start Program
Department of Industry, Tourism and Resources
Industry Research and Development Board

Audit Report No.14 Performance Audit
Administration of the Commonwealth State Territory Disability Agreement
Department of Family and Community Services

Audit Report No.13 Performance Audit
Administration of Goods and Services Tax Compliance in the Large Business Market Segment
Australian Taxation Office

Audit Report No.12 Performance Audit
Review of the Evaluation Methods and Continuous Improvement Processes for Australia's National Counter-Terrorism Coordination Arrangements
Attorney-General's Department
The Department of the Prime Minister and Cabinet

Audit Report No.11 Business Support Process Audit
The Senate Order for Departmental and Agency Contracts (Calendar Year 2004 Compliance)

Audit Report No.10 Performance Audit
Upgrade of the Orion Maritime Patrol Aircraft Fleet
Department of Defence
Defence Materiel Organisation

Audit Report No.9 Performance Audit
Provision of Export Assistance to Rural and Regional Australia through the TradeStart Program
Australian Trade Commission (Austrade)

Audit Report No.8 Performance Audit
Management of the Personnel Management Key Solution (PMKeyS) Implementation Project
Department of Defence

Audit Report No.7 Performance Audit
Regulation by the Office of the Gene Technology Regulator
Office of the Gene Technology Regulator
Department of Health and Ageing

Audit Report No.6 Performance Audit
Implementation of Job Network Employment Services Contract 3
Department of Employment and Workplace Relations

Audit Report No.5 Performance Audit
A Financial Management Framework to support Managers in the Department of Health and Ageing

Audit Report No.4 Performance Audit
Post Sale Management of Privatised Rail Business Contractual Rights and Obligations

Audit Report No.3 Performance Audit
Management of the M113 Armoured Personnel Carrier Upgrade Project
Department of Defence

Audit Report No.2 Performance Audit
Bank Prudential Supervision Follow-up Audit
Australian Prudential Regulation Authority

Audit Report No.1 Performance Audit
Management of Detention Centre Contracts—Part B
Department of Immigration and Multicultural and Indigenous Affairs

Better Practice Guides

Preparation of Financial Statements by Public Sector Entities	Apr 2006
Administration of Fringe Benefits Tax	Feb 2006
User–Friendly Forms Key Principles and Practices to Effectively Design and Communicate Australian Government Forms	Jan 2006
Public Sector Audit Committees	Feb 2005
Fraud Control in Australian Government Agencies	Aug 2004
Security and Control Update for SAP R/3	June 2004
AMODEL Illustrative Financial Statements 2004	May 2004
Better Practice in Annual Performance Reporting	Apr 2004
Management of Scientific Research and Development Projects in Commonwealth Agencies	Dec 2003
Public Sector Governance	July 2003
Goods and Services Tax (GST) Administration	May 2003
Managing Parliamentary Workflow	Apr 2003
Building Capability—A framework for managing learning and development in the APS	Apr 2003
Internal Budgeting	Feb 2003
Administration of Grants	May 2002
Performance Information in Portfolio Budget Statements	May 2002
Life-Cycle Costing	Dec 2001
Some Better Practice Principles for Developing Policy Advice	Nov 2001
Rehabilitation: Managing Return to Work	June 2001
Internet Delivery Decisions	Apr 2001
Planning for the Workforce of the Future	Mar 2001
Contract Management	Feb 2001
Business Continuity Management	Jan 2000
Building a Better Financial Management Framework	Nov 1999

Building Better Financial Management Support	Nov 1999
Managing APS Staff Reductions (in Audit Report No.49 1998–99)	June 1999
Commonwealth Agency Energy Management	June 1999
Cash Management	Mar 1999
Security and Control for SAP R/3	Oct 1998
Selecting Suppliers: Managing the Risk	Oct 1998
New Directions in Internal Audit	July 1998
Controlling Performance and Outcomes	Dec 1997
Management of Accounts Receivable	Dec 1997
Protective Security Principles (in Audit Report No.21 1997–98)	Dec 1997
Public Sector Travel	Dec 1997
Audit Committees	July 1997
Management of Corporate Sponsorship	Apr 1997
Telephone Call Centres Handbook	Dec 1996
Paying Accounts	Nov 1996
Asset Management Handbook	June 1996