Appendix 1
Processes Leading to PBAC Consideration – Annual Report for 2015-16

Introduction

This is the seventh annual report to the Parliament on the processes leading to the consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) of applications for recommendation for listing of items on the Pharmaceutical Benefits Scheme (PBS). This report covers the 2015-16 financial year.

This annual report has been prepared pursuant to subsection 99YBC(5) of the *National Health Act 1953* (the Act), under which it is required that:

> *The Secretary must, as soon as practicable after June 30 each year, prepare an annual report on the processes leading up to Pharmaceutical Benefits Advisory Committee consideration, including:*
>
> *a) the extent and timeliness with which responsible persons are provided copies of documents relevant to their submissions to the Pharmaceutical Benefits Advisory Committee;*
>
> *b) the extent to which responsible persons exercise their right to comment on these documents, including appearing at hearings before the Pharmaceutical Benefits Advisory Committee; and*
>
> *c) the number of responsible persons seeking a review of the Pharmaceutical Benefits Advisory Committee recommendation.*

PBAC Cost Recovery Reform

Cost recovery for processes leading to PBAC consideration commenced on 1 January 2010.

Background

Cost recovery policy is administered by the Department of Finance and is outlined in the Australian Government Cost Recovery Guidelines. The underlying principle of the policy is that entities should set charges to recover all the costs of products or services where it is efficient and effective to do so, where services will be provided to an identified group and where charging is consistent with Australian Government policy objectives.

PBS Cost Recovery Regulations

Section 140 of the Act provides in part, that the:

> *Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act.*

Division 4C of Part VII of the Act enables fees to be charged for certain services provided by the Australian Government in order to recover the cost to the Commonwealth of providing those services. Those services relate to the exercise of certain powers of the Minister for Health under section 9B of the Act (which relates to the National Immunisation Program (NIP)) and under Part VII of the Act (which relates to the PBS). The services include the functions of PBAC and its sub-committees; and related functions performed by officers, administrative staff, contractors and sub-contractors of the Department.

Section 99YBA of the Act provides for regulations to set out the fees that are payable for those services, as well as other matters relating to the payment of those fees and the provision of those services, including some consequences of failing to pay a fee.

The regulations prescribe application categories, fees and application procedures to applicants seeking a new or amended inclusion in the PBS or NIP. The regulations also provide for the exemption from fees, waiver of fees, and for review rights and procedures. The fees and procedures are administered by the Department of Health.

PBAC

The PBAC is established under section 100A of the Act and is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and a consumer representative. In 2015, provision was made for appointment of an industry representative and additional consumer representative. Its primary role is to recommend new medicines for listing on the PBS and the inclusion of vaccines on the NIP. No new medicine can be listed unless the committee makes a positive recommendation to the Minister for Health. The PBAC holds three scheduled meetings each year, usually in March, July and November.

When recommending a medicine for listing, the PBAC takes into account the medical condition(s) for which the medicine was registered for use in Australia and its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments, including non-medical treatments.

The PBAC has two sub-committees to assist with analysis and advice in these areas. They are:

- **The Economics Sub-Committee (ESC)** which assesses clinical and economic evaluations of medicines submitted to the PBAC for listing, and advises the PBAC on the technical aspects of these evaluations; and
- **The Drug Utilisation Sub-Committee (DUSC)** which assesses estimates on projected usage and the financial cost of medicines. It also collects and analyses data on actual use (including in comparison with different countries), and provides advice to the PBAC.

Roles of the PBAC

The PBAC performs the following roles:

- recommends medicines and medicinal preparations to the Minister for Health for funding under the PBS;
- recommends vaccines to the Minister for funding under the NIP (since 2006);
- advises the Minister and Department about cost-effectiveness;
- recommends maximum quantities and repeats on the basis of community use, and any restrictions on the indications where PBS subsidy is available;
- regularly reviews the list of PBS items; and
- advises the Minister about any other matters relating to the PBS, including on any matter referred to it by the Minister.

Requirements of section 99YBC of the Act

a) Extent and timeliness of the provision of relevant documents to responsible persons

Subsection 99YBC(5)(a) of the Act requires that the Minister report to the Parliament on the extent and timeliness of the provision of relevant documents to responsible persons. The PBAC provides responsible persons with documents relevant to their submissions in an orderly, timely and transparent fashion. This is achieved through the well-established practice of providing responsible persons with documents relevant to their submissions six weeks before the applicable PBAC meeting. These documents are referred to as 'commentaries'.

Applicants' pre-sub-committee response(s) are received by the PBAC Secretariat five weeks before the relevant PBAC meeting. Following the meeting of PBAC sub-committees, the PBAC Secretariat provides relevant sub-committee papers to responsible persons two weeks before the relevant PBAC meeting. Sponsors then provide their responses to the PBAC Secretariat one week before the PBAC meeting.

Following the PBAC meeting the PBAC Secretariat provides verbal advice on the outcomes of PBAC consideration to the relevant sponsor half a week after the meeting, with written advice provided three weeks (positive recommendations) and five weeks (all other recommendations) after the relevant PBAC meeting.

Where requested, the PBAC Secretariat, the PBAC and its sub-committees provide informal access to departmental officers and formal access to the PBAC for responsible persons or their representative, including the option for the sponsor to appear before the PBAC in person.

b) Extent to which responsible persons comment on their commentaries

Subsection 99YBC(5)(b) of the Act requires that the Minister report to the Parliament on the:

> *'…extent to which responsible persons exercise their right to comment on these documents, including appearing at hearings before the Pharmaceutical Benefits Advisory Committee;'*

During 2015-16, the PBAC held three ordinary meetings (as is usual practice) and considered a total of 97 major submissions. For the:

- **July 2015 PBAC meeting**, 27 responsible persons lodged major submissions. 27 sponsors responded to their commentaries.
- **November 2015 PBAC meeting**, 34 responsible persons lodged major submissions. 34 sponsors responded to their commentaries.
- **March 2016 PBAC meeting**, 36 responsible persons lodged major submissions. 35 sponsors responded to their commentaries and one sponsor withdrew its submission before responding to its commentary.

Consequently, of the 96 major submissions considered by PBAC in 2015-16, 96 responsible persons exercised their right to respond to their commentaries.

c) Number of responsible persons seeking a review of PBAC recommendations

Subsection 99YBC(5)(c) of the Act requires that the Minister report to the Parliament on the:

> *'…number of responsible persons seeking a review of the Pharmaceutical Benefits Advisory Committee recommendation.'*

During the 2015-16 financial year, there were no requests to the PBAC for an Independent Review.

Number and category of applications for each PBAC meeting in 2015-16

July 2015 PBAC Meeting

Category	Number	Comments
Major	27	–
Minor	26	Included 1 secretariat listing

November 2015 PBAC Meeting

Category	Number	Comments
Major	34	–
Minor	43	Included 4 secretariat listings

March 2016 PBAC Meeting

Category	Number	Comments
Major	36	–
Minor	38	Included 2 secretariat listings

Secretariat listings are not considered as a separate agenda item at a meeting of the Committee as they are very minor amendments to existing listings. However, all secretariat listings are still decided by the Committee on the merit of each application based on the papers provided to the Committee.

Withdrawn applications for each PBAC meeting in 2015-16 by category and reasons for withdrawal of applications for each meeting

July 2015 PBAC Meeting

Category	Number	Reasons for withdrawal
Major	0	–
Minor	1	Decision by applicant – no reason provided

November 2015 PBAC Meeting

Category	Number	Reasons for withdrawal
Major	0	–
Minor	2	Decision by applicants – no reason provided

March 2016 PBAC Meeting

Category	Number	Reasons for withdrawal
Major	1	Decision by applicant – no reason provided
Minor	1	Decision by applicant – no reason provided

Number of responsible persons that responded to their commentaries, including appearing before PBAC meetings

All of the responsible persons who submitted a major submission to PBAC during 2015-16 responded to their commentary.

July 2015 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
27	27	6

November 2015 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
34	34	9

March 2016 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
36 (1 subsequently withdrawn)	35	16

Number of pre-submission meetings held in 2015-16

Pre-submission meetings per month	Meetings held
2015	
July	0
August	10
September	6
October	2
November	0
December	5
2016	
January	4
February	2
March	2
April	6
May	7
June	3
Total	47

Figures do not take into account extended meetings where two or more drugs are discussed within one meeting date.