Appendix 1: Processes Leading to PBAC Consideration – Annual Report for 2016-17

Introduction

This is the eighth 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 2016-17 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 in each year, prepare and give to the Minister a report on processes leading up to the Pharmaceutical Benefits Advisory Committee consideration, including:*
>
> *a) the extent and timeliness with which responsible persons are provided copies of documents relevant to their submission 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;*
>
> *c) the number of responsible persons seeking a review of the Pharmaceutical Benefits Advisory Committee recommendation.*

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 and health economists, as well as industry and consumer nominees. Its primary role is to consider medicines for listing on the PBS and vaccines for inclusion 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 considering 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 three 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;
- **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; and
- **The Nutritional Products Working Party (NPWP)** which advises the PBAC on matters relating to the effectiveness and use of therapeutic foods and nutritional products.

Roles of the PBAC

- 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

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-subcommittee 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 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

During 2016-17, the PBAC held three ordinary meetings (as is usual practice) and considered a total of 97 major submissions. For the:

- **July 2016 PBAC meeting**, 20 responsible persons lodged major submissions. 20 sponsors responded to their commentaries.
- **November 2016 PBAC meeting**, 31 responsible persons lodged major submissions. 31 sponsors responded to their commentaries.
- **March 2017 PBAC meeting**, 21 responsible persons lodged major submissions. 21 sponsors responded to their commentaries and one sponsor withdrew its submission before responding to its commentary.

Consequently, of the 72 major submissions considered by PBAC in 2016-17, 72 responsible persons exercised their right to respond to their commentaries.

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

During the 2016-17 financial year, there were no requests to the PBAC for an Independent Review.

Number and category of applications for each PBAC meeting in 2016-17[76]

July 2016 PBAC Meeting

Category	Number
Major	20
Minor	28

November 2016 PBAC Meeting

Category	Number
Major	31
Minor	37

March 2017 PBAC Meeting

Category	Number
Major	21
Minor	23

Number and category of withdrawn applications for each PBAC meeting in 2016-17

July 2016 PBAC Meeting

Category	Number	Reasons for withdrawal
Major	3	Decision by applicants – no reason provided
Minor	0	–

November 2016 PBAC Meeting

Category	Number	Reasons for withdrawal
Major	3	Decision by applicants – no reason provided
Minor	3	Decision by applicants – no reason provided

March 2017 PBAC Meeting

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

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

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 2016-17 responded to their commentary.

July 2016 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
20	20	5

November 2016 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
31	31	13

March 2017 PBAC Meeting

Number of major submissions	Number of responsible persons that responded to their commentaries	Number of responsible persons that appeared before PBAC
21	21	6

Number of pre-submission meetings held in 2016-17[77]

Pre-submission meetings per month	Meetings held
2016	
July	0
August	9
September	5
October	2
November	0
December	6
2017	
January	4
February	2
March	1
April	7
May	7
June	1
Total	**44**

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