

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2013-14, 5/6 & 7 June 2013

Question: E13-228

OUTCOME: 2 – Access to Pharmaceutical Services

Topic: Pharmaceutical Benefits Advisory Committee Submissions

Type of Question: Written Question on Notice

Senator: Fierravanti-Wells

Question:

Over the last five years (broken down by year):

- a) How many major submissions were received by the PBAC?
- b) How many of those received a positive recommendation?
- c) How many in turn have been listed by the Government and are available on the PBS?

Answer:

The Department of Health and Ageing currently publishes key activity indicators for the Pharmaceutical Benefits Scheme on the Departmental website at <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-activity-indicators>. The indicators are a set of outcomes, based on calendar years, resulting from a collaborative project between Medicines Australia, the Department and the Pharmaceutical Benefits Advisory Committee (PBAC).

As of 23 October 2013

Question	2008	2009	2010
a) How many major submissions were received by the PBAC?	93	73	71
b) How many of those received a positive recommendation?	43	39	38
c) How many in turn have been listed by the Government and are available on the PBS?	43	36	34

NOTES:

- Does not include special meetings
- Does not include withdrawals

With respect to the period 2011 to the present date, figures cannot yet be independently

verified as not all PBS Public Summary Documents (PSDs) for major cost effectiveness submissions to PBAC from 2011 to the present date have been published. With the introduction of the PBAC/Therapeutic Goods Administration (TGA) parallel processing as part of the Memorandum of Understanding with Medicines Australia, the PBAC outcome for a product submitted under the parallel process is not published until the TGA delegate's overview of the relevant medicine is made available. Parallel processing is where a sponsor may submit an application to the PBAC for PBS listing before the registration of the medicine for the requested indication is finalised by the TGA.

In accordance with the 'Framework for the introduction of parallel processes' agreed with Medicines Australia, the Department cannot publish PSD's until the medicine is added to the Australian Register of Therapeutic Goods for the indication seeking PBS listing. This practice stems from industry sensitivities regarding potential disclosure of commercially confidential information. Additionally, were the Department to publish a positive PBAC recommendation for a product before the TGA outcome is known, this may be viewed as possibly prejudicing the TGA process. The Department does not publish indicative statistics on PBAC outcomes until all individual outcomes are published to ensure that these statistics can be independently verified.