

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 31 May 2011

Question: E11- 521

OUTCOME 2: Access to Pharmaceutical Services

Topic: TIME TO LIST MEDICINES ON THE PBS

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Senator Feirravanti-Wells asked:

What is the current length of time taken for a medicine to go from being recommended by PBAC to being listed on the PBS and how does this compare over the past five years?

Answer:

The length of time from the recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) to listing on the Pharmaceutical Benefits Scheme (PBS) varies depending on a number of factors, such as whether:

- the application claims superiority over an existing PBS listed medicine;
- the application claims there is no additional health outcome gained;
- pricing is in accordance with the Pharmaceutical Benefits Pricing Authority (PBPA) criteria;
- pricing arrangements require negotiation;
- a risk share arrangement or a Deed of Agreement requires negotiation;
- Cabinet consideration is required; and
- the company can supply on the proposed PBS listing date.

The Memorandum of Understanding (MoU) with Medicines Australia actually measures the timeframe between pricing agreement and Cabinet consideration in recognition of the variability of these factors.

There has been no change to PBAC assessment timeframes, and for those changes to the PBS with no financial impact there has been no change in the listing timeframes.

Apart from those medicines and price increases that remain deferred, additions and changes to the PBS recommended by PBAC and PBPA in November 2010 and December 2010, and that were considered by the Cabinet under the new arrangements, were generally listed in accordance with established timeframes (that is by 1 April 2011).

In line with the terms of the MoU, the consideration by the Cabinet of high cost medicines romiplostim (Nplate®), levodopa with carbidopa (Duodopa®) and fingolimod (Gilenya®) occurred within six months of pricing agreement between the Department and the sponsoring companies. Specific timeframes for each medicine's consideration are in the table below.

**Table 1: High cost drugs considered by the Cabinet since the MoU**

<b>Medicine</b>	<b>Indication</b>	<b>Date recommended by PBAC</b>	<b>Date price agreed</b>	<b>Time to cabinet consideration</b>	<b>Date of PBS listing</b>
Romiplostim (Nplate®)	Rare blood disorder	July 2010	August 2010	6 months	1 April 2011
Levodopa with carbidopa (Duodopa®)	Advanced Parkinson disease	Nov 2010	January 2011	1 month	1 May 2011
Fingolimod (Gilenya)	Multiple sclerosis	March 2011	May 2011	1 month	Expected Sep 2011

An extension to the PBS listing for cetuximab (Erbix®) to treat metastatic colorectal cancer (bowel cancer) in patients with K-RAS wild type disease was recommended by PBAC at its July 2010 meeting and its price was agreed on 29 September 2010. To determine whether a patient has K-RAS wild type disease, a genetic test is required. This test is currently not funded through the Medicare Benefits Schedule (MBS).

The manufacturer of cetuximab only applied for the MBS listing of the genetic test after PBAC made its recommendation. The listing of cetuximab was complex given that it is the first time this Government has listed a medicine on the PBS while also seeking to list a co-dependent genetic test on the MBS. While the assessment of listing the genetic test on the MBS is still ongoing, the drug manufacturer has offered to pay for the genetic test in the meantime. Subject to listing conditions being met the extension to the PBS listing of cetuximab will occur on 1 September 2011.

With respect to the time between PBAC consideration and PBS listing, the average time for those submissions, estimated to cost more \$10 million in any of the first four years of listing is as follows.

**Table 2:**

<b>Calendar Year of Listing</b>	<b>Average Time from PBAC recommendation to Listing Date</b>
2006	6.7 months
2007	7.5 months
2008	8.0 months
2009	11.0 months
2010	Nil. No high cost medicines listed.