

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Budget Estimates 2014 - 2015, 2/3 June 2014

Ref No: SQ14-000515

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Post Market Reviews

Type of Question: Written Question on Notice

Senator: Brown, Carol

Question:

a) Page 71 of the Health Portfolio Budget Statement states that, “In 2014-15, the Government will progress several reviews of medicines in use, focusing on the appropriate and quality use of medicines to help improve health outcomes for patients and ensure continued value for money for taxpayers”.

Please provide a list of all current and planned reviews of medicines.

b) In the context of these reviews how is “continued value for money for taxpayers” determined?

c) Please outline the engagement framework for these post market reviews.

Answer:

a) Post-market Reviews in progress are:

- Asthma Medicines in Children;
- Products used in the management of diabetes:
 - Stage 1: Blood Glucose Test Strips:
 - Stage 2: Insulin Pumps:
 - Stage 3: Type 2 Diabetes Medications:
- Authority Required Pharmaceutical Benefits Scheme (PBS) Listings; and
- The Life Saving Drugs Programme.

b) The Government has introduced a systematic post-market approach to monitoring medicines in use to inform decision making at all levels throughout the medicine cycle (from the registration of a medicine right through to its use by consumers).

Applications to list a medicine on the Pharmaceutical Benefits Scheme are considered by the Pharmaceutical Benefits Advisory Committee (PBAC) on a case-by-case basis at the time a submission for listing is made. This means that a medicine is only considered in the context of treatments and evidence available at that time. Over time, more evidence on individual medicine’s safety and efficacy becomes available, more data become available about utilisation in real clinical practice, and/or treatment practices evolve.

The post-market review process provides a mechanism for medicines to be considered in the full and current treatment context, including actual utilisation, any new evidence on comparative efficacy and safety, and the latest treatment guidelines. The Review process undertakes to compare the expected utilisation, effectiveness, and proposed place in therapy of the medicine that was considered cost-effective by the PBAC at the time of the initial listing with the most recent information on comparative effectiveness and current utilisation. After considering any new information identified during the review and the previous recommendation, the PBAC may make further recommendations to the Minister to ensure that the medicines continue to provide value for money to taxpayers.

Reviews of cost-effectiveness ensure that the cost of medicines to the PBS appropriately reflects the health outcomes expected and subsequently produced in the 'real world'.

- c) The process for conducting post-market reviews is available at:
<http://www.pbs.gov.au/info/reviews/subsidised-medicines-reviews>.

Each review has terms of reference, which are public, and are preceded by public consultation on draft terms of reference.

Open public submission processes are also undertaken for all post-market reviews.

Stakeholder forums are held after the initial written submission process to provide a further opportunity for input. Individuals who made a submission to the Review are invited to attend and the Department ensures consumer representation by contacting consumer advocacy groups.

An 'issues and options paper' and/or 'draft report' are made available for stakeholder comment. This provides further opportunity for stakeholders to provide additional evidence or comments on Reviews for consideration by the PBAC and the Government.

While a significant amount of information is already publicly available, the Department is currently working with Medicines Australia through the Access to Medicines Working Group to develop further information which will assist sponsors to participate in the review process.