Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 13 & 15 February 2013

Question: E13-155

OUTCOME 2: Access to Pharmaceutical Services

Topic: PBAC Review

Type of Question: Written Question on Notice

Senator: Senator Di Natale

Question:

a) Please explain the function and process under which a PBAC Review is undertaken and what references are made to current prescribing information, peer review groups and colleges.
b) What external expert sources does the PBAC consult as part of its process in developing recommendations in these reviews?
c) Are these sources generally regarded as key opinion leaders by their peer groups and colleges? How are they chosen?
d) Are these reviews, if they are cost-based, done with the best clinical advice and on the principles of sound evidence based medication? How can the government and taxpayers be sure of that?
e) What further reviews are expected and which categories of drugs will they cover?
f) In the current PBAC Review into Diabetes Prescribing, is the intention of the Department to restrict access to some drugs, namely glitazones and DPP4s (gliptins)? Why does the Department intent to restrict access to these drugs at a time when Diabetes, a national health priority is a serious health issue in this country?
g) Are there implications for insulin pricing in this review? Is it not true Australia already have some of the lowest insulin prices in the world?
h) Is the Department advising the government on how to cut access to drugs that are needed for treating serious conditions only because of their cost?
i) With the recently announced PBAC Review into the Life Saving Drugs Programme, what practical implications are there for patients currently dependent on these drugs?
j) Has the Department discussed with the government whether patients will be affected if the government decides to reduce funding for these drugs? Are there plans to remove drugs on the LSDP?
k) Has the Department consulted with any patient groups likely to be affected?

Answer:

a) and 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).

Post-market reviews fall under the quality use of medicines objective of the National Medicines Policy framework. This includes promoting the safe and effective use of medicines, with the aim to improve health outcomes for all Australians.

It is important for the Government to continue to monitor clinical and cost-effectiveness of medicines after they have been listed on the PBS. These reviews assess both appropriateness of need, as well as considering the effect of utilisation. Reviews of cost-effectiveness ensure that the cost of medicines to the PBS appropriately reflects the health outcomes expected and subsequently produced.

The majority of requests for a post-market review are recommendations by the PBAC, due to issues identified through the routine monitoring and evaluation processes of the Drug Utilisation Sub-Committee (DUSC). The framework has a degree of flexibility, however, to allow for reviews initiated from other sources, such as the Senate request for a review of high potency statins.

Post-market reviews follow a standard, transparent process that is clearly outlined for the public on the PBS website. Once initiated, each post-market review includes:

- An agreed terms of reference;
- A six-week period of public consultation;
- Reviews of the safety, effectiveness, utilisation and cost-effectiveness of the medicines, contracted out to independent research organisations and universities;
- Development of an 'issues and options paper' and/or 'draft report', made available for public comment; and
- Development of a final report containing the review findings for consideration and recommendation.

For the first time as a part of these reviews, all stakeholders, including consumers have the opportunity to input to the review process, not just industry. This consumer input helps to determine impact and clinical need.

In addition, where required, an expert Reference Group is established to assist the Department in conducting the review and to explore options to source relevant evidence to inform the review. These groups do not make recommendations to the Government; they help to establish the evidence for consideration. The Department also contracts independent academic or specialist experts to search and collate published evidence for consideration as a part of the review.

c) Yes. The majority of members are nominated by their relevant organisation or peak body, or are selected based on their expertise and positions within peak bodies, and therefore represent key researchers and opinion leaders in the field. Members of PBAC or its sub-committees may also be invited to participate.

Reference Group members may include, but are not limited to:

- independent specialist clinicians and nurse practitioners;
- researchers and representatives from peak bodies in the relevant field;
- general practitioners;
- health educators;
- health economists;
- dietitians;
- psychologists;
- health consumer representatives or advocates; and
- representatives from the National Prescribing Service, Therapeutic Goods Administration (TGA) and the National Health and Medical Research Council (NHMRC).

d) When a new medicine is approved, it is virtually impossible to know all of the risks that a population may encounter when using that product. Although the Therapeutic Goods Administration requires drug manufacturers to meet rigorous standards demonstrating the drug's safety and effectiveness for its intended use, once approved, medicines can be used by different populations to those studied in clinical trials. This is why post-market reviews are so important to ensure medicines continue to be used in the manner recommended by the PBAC.

Post-market reviews may be initiated due to concerns related to the quality use of a medicine, cost effectiveness, clinical effectiveness, higher than predicted utilisation and/or international differences.

As well as a full and transparent public consultation process, the Department seeks advice from a range of experts when conducting post-market reviews, including the PBAC and its sub-committees if necessary, on the scope and potential sources of evidence and input for post-market reviews. Post-market reviews are progressed with the same level of scrutiny and rigour as existing PBAC processes.

e) The Department cannot pre-empt which categories of medicines may be recommended for review. There are currently two post-market reviews in progress:

- Medicines used to treat asthma in children.
- Medicines and products used to manage diabetes.

f) Consistent with this national health priority, the objective of the Post-Market Review of Products Used in the Management of Diabetes is to evaluate diabetes interventions to ensure that Australians have access to and are using products consistent with best clinical practice.

The Review will systematically evaluate the body of clinical evidence regarding diabetes interventions, in the context of current national and international guidance. Evidence gathered will be used to improve quality use of medicines and health outcomes for people with diabetes. The Review is still underway and any advice that the PBAC may provide to Government as a result of its consideration of the Review, cannot be pre-empted.

g) No, this Review focuses on oral anti-diabetic medicines used in the management of type 2 diabetes, blood glucose test strips, and insulin pumps. However, to appropriately capture the context in which these medicines are being prescribed insulin needs to be considered, but is not the focus of this Review.

h) No. The purpose of post-market reviews of PBS-listed medicines is to improve health outcomes and ensure the clinical and cost-effective use of medicines. Some previous reviews have increased access, with the flow on effect of added cost to the PBS, such as a review of the use of clopidogrel.

i) to k)
There was no recent announcement about a review into the Life Saving Drugs Program (LSDP).

However, the Australian Government completed a review of the LSDP in 2009. The purpose of the review was to examine the LSDP with a view to establishing consistent and rigorous procedures and ensuring sustainability.

The Review was informed by a range of information and views, including clinical literature and research; international policies, guidelines and experiences; and through consultation with many stakeholders in the program, including consumer representatives, expert clinicians and industry representatives.

Further information about the review of the LSDP in 2009 is available on the Department of Health and Ageing's website at
www.health.gov.au/internet/main/publishing.nsf/Content/lsdp-preview