Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 30 May 2011

Question: E11-509

OUTCOME 2: Access to Pharmaceutical Services

Topic: PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) RECOMMENDATION - NAFARELIN

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Senator Boyce asked:

a) So, it has a clinical need and you hope that the costs to the PBS system will drop?

b) Did both of these companies write back to you asking about whether they would have to pay the application fee?

c) Did both of them pay the application fee?

d) Can you tell me the whole background of the fees, whether they asked for a waiver and what they ended paying for?

Answer:

a) At its November 2009 meeting, the PBAC recommended the listing of ganirelix (ORGALUTRAN®) on the Pharmaceutical Benefits Scheme (PBS) in the Section 100 IVF/GIFT Program for the prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation, followed by oocyte pick-up and assisted reproductive techniques. This medicine was listed on the PBS on 1 August 2010.

In making the recommendation, the PBAC considered there was a clinical need for gonadotropin releasing hormone (GnRH) analogues on the IVF/GIFT Program.

On 23 December 2009, the PBAC Secretariat wrote to both Pfizer Pty Limited (manufactuer of nafarelin) and Merck Serono Australia Pty Ltd (manufactuer of cetrorelix), inviting them to make minor submissions to the PBAC to seek listing of nafarelin and cetrorelix, respectively, in the Section 100 IVF/GIFT Program.

On 3 May 2010, Merck Serono Australia Pty Ltd lodged a submission with the PBAC Secretariat for consideration at the July 2010 meeting. Following PBAC's recommendation from this meeting, cetrorelix was listed on the PBS on 1 December 2010.

A submission from Pfizer Pty Limited in respect of nafarelin was not received by the PBAC Secretariat until 20 August 2010 and it was considered at the November 2010 PBAC meeting. Nafarelin had no additional health outcome over ganirelix and cetrorelix, but had a net cost.

b) No, only Pfizer sought a waiver of the evaluation fee.

c) Yes, both companies paid the standard evaluation fee for a minor submission of $12,500. An invitation to make a submission to the PBAC does not lead to an automatic waiver or exemption from cost recovery fees. Companies make application to the PBAC in full knowledge of the fees payable.

Each company paid the standard evaluation fee for a minor submission of $12,500 when they applied to list cetrorelix (CETROTIDE®) and nafarelin (SYNAREL®) respectively on the PBS.

d) Cost recovery fees for PBS listing and evaluation processes have been in place since 1 January 2010 following amendments to Part VII of the National Health Act 1953. The grounds in which a waiver or exemption may be granted are defined in the Regulations. The sequence of events relating to cost recovery fees paid by Pfizer and Merck Serono is provided below.

Cetrorelix (CETROTIDE®) *(Merck Serono)*

- 3 May 2010 – Merck Serono application received for cetrorelix to be considered at the July 2010 PBAC meeting.
- 18 June 2010 - evaluation invoice (minor submission) for $12,500 sent.
- 9 Feb 2011 - pricing invoice (secretariat listing) for $1000 sent.

Nafarelin (SYNAREL®) *(Pfizer)*

- 20 August 2010 - Pfizer application received for nafarelin to be considered at the November 2010 PBAC meeting. The company seeks a waiver of the cost recovery evaluation fee.
- 29 October 2010 - evaluation fee waiver declined and evaluation invoice (minor submission) for $12,500 sent.
- No pricing invoice sent as PBS listing of the medicine was deferred.