Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2015 - 2016, 10 February 2016

Ref No: SQ16-000020

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Biosimilars

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

a) Last year Eli Lilly were about to bring a biosimilar product onto the market that had conflicting advice from PBAC and TGA – one said it was safe and should be listed (PBAC) the other said they had concerns (TGA) so the product wasn't listed. What happened as a result of this confusion?

Answer:

The Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee (PBAC) have separate roles in the evaluation of biosimilar medicines. The TGA uses quality, safety and efficacy to determine whether the biosimilar is equally safe and effective as the reference medicine. Where the TGA has determined the biosimilar is equally safe and effective as the reference medicine the biosimilar will be included on the Australian Register of Therapeutic Goods, the biosimilar can then be supplied in Australia.

Once the TGA has determined this the PBAC can assess a submission from the drug sponsor to have the biosimilar listed on the Pharmaceutical benefits Scheme (PBS). Where PBAC recommends a biosimilar for listing on the PBS, it will also consider whether the biosimilar and its reference medicine should be substitutable.

There was clarification of TGA guidance material about product information for biosimilar products in December 2015.

Recommendations made by PBAC in November 2015, relating to the listing of drugs on the PBS, can be found at: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/recommendations-pbac-november-2015

The sponsor of this particular product currently has the option of listing on the PBS as recommended by the PBAC.