

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2014 - 2015, 25 February 2015

Ref No: SQ15-000103

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Pharmaceutical Benefits Scheme Listing

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

When the PBAC was negotiating with Vertex (Kalydeco sponsor) were they aware that there would be another application for people with CF with the R117h mutation and even though Kalydeco for R117h has been approved by the FDA in the US and it has been approved by the TGA for use in Australia by people with CF with the G551D mutation, the approval process may take another year?

Answer:

R117h is a different mutation to those currently listed on the Pharmaceutical Benefits Scheme, and was not part of the submissions considered in July 2013, November 2013 or March 2014.

Medicines cannot be recommended for subsidy by the Pharmaceutical Benefits Advisory Committee (PBAC) unless the medicine is approved for marketing in Australia for that indication. Further, the PBAC can only consider the subsidy for a drug in the indication requested by the sponsoring company, which has the clinical evidence necessary to demonstrate clinical effectiveness and costs effectiveness for that indication.

Confidentiality requirements restrict the release of information by the Therapeutic Goods Administration (TGA) about the details of an application to either include or extend the indications of a medicine on the Australian Register of Therapeutic Goods (ARTG). This includes the release of information about whether any application has even been received. This is an industry agreed convention. Therefore, the Department of Health is not able to provide information on whether an application to the TGA has been made to extend the indications of ivacaftor (Kalydeco®) to include patients with R117h mutation. If the sponsor chooses to make a submission for reimbursement of ivacaftor for these patients, this submission will be considered by the PBAC.