

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH PORTFOLIO

Additional Estimates 2014 - 2015, 25 February 2015

Ref No: SQ15-000102

OUTCOME: 2 - Access to Pharmaceutical Services

Topic: Pharmaceutical Benefits Scheme Listing

Type of Question: Written Question on Notice

Senator: Di Natale, Richard

Question:

Regarding the drug Kalydeco and the problems in access, I have been approached by a mother of two facing \$25,000 a month to buy the R117h variant that is a Vertex product. What options are available to this person as there appears to be a wait of up to 2 years?

Answer:

The timing of when a medicine is considered by the Pharmaceutical Benefits Advisory Committee (PBAC) is a decision made by the manufacturer of the medicine, not by the Government or the PBAC. The PBAC cannot compel a company to apply for listing on the Pharmaceutical Benefits Scheme (PBS) but will accept a submission to do so at any time.

Medicines cannot be recommended for subsidy by the 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 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.

The patient's treating doctor may choose to contact the sponsor of ivacaftor, Vertex Pharmaceuticals, to see if this medicine could be supplied via a compassionate access program.