

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-266

OUTCOME 2: Access to Pharmaceutical Services

Topic: SOLIRIS

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) In March 2009 the Pharmaceutical Benefits Advisory Committee (PBAC) recommended that the government put the life Saving the government consider funding of the drug Soliris via the Life Saving Drug Program (LSDP) for treatment of Paroxysmal Nocturnal Haemoglobinuria (PNH). Has the drug been listed on the LSDP as yet?
- b) Is it the case that on May 10 this year - one day before the Budget - the Department of Health and Ageing released new criteria for funding LSDP applications and the Budget the next day provided no new funding for the LSDP program?
- c) Did the Minister send Soliris back to the PBAC for re-consideration and state in a Press Release on May 20 that - and I quote - "due to the uncertainty outlined by the PBAC on the effectiveness of Soliris the Government was not able to fund Soliris through the LSDP in the 2010-11 Budget. Soliris is one of the world's most expensive drugs"?
- d) Did the PBAC in August this year re-confirm that this drug met all of the new LSDP criteria and again recommended its funding - stating that -Soliris dramatically reduced mortality for PNH patients with unequivocal statistical significance; that there is a high certainty of a better outcome with Soliris against Basic Standard Care and a very high level of confidence in survival with Soliris is substantial; that the price proposed for Soliris in Australia is less than prices paid overseas; and that the price is less for adults than other drugs in the LDSP program? Now that the Government has had this information for more than two months does the department know when the Minister and Cabinet will make a decision to fund and provide access to this life saving medicine?

Answers:

- a) Yes, on 9 December 2010 the Minister for Health and Ageing announced that Soliris would be subsidised through the Life Saving Drugs Program from 1 January 2011 to treat Paroxysmal Nocturnal Haemoglobinuria.
- b) Revised funding Criteria and Conditions for the Life Saving Drugs Program became effective on 10 May 2010, following extensive consultation with affected stakeholders during the period March 2010 to April 2010.
- c) Yes.

- d) As published on 29 October 2010 in the PBAC Public Summary Document, on 13 August 2010, the PBAC recommended that Soliris be considered by the Government to be subsidised through the LSDP, on the grounds,
“... that the additional evidence, including that presented by the sponsor and unpublished data, acceptably supported the prediction that a patient’s lifespan with classic PNH would be substantially extended as a direct consequence of treatment with eculizumab compared to best supportive care ...”

There are several matters that must be finalised before Government consideration can occur, including pricing negotiations, risk share arrangements and the establishment of a Disease Advisory Committee to set and monitor eligibility criteria for access to the drug.

These matters have now been finalised and as outlined above in a), Soliris will be funded through the LSDP from 1 January 2011.