# **Senate Community Affairs Committee**

# ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

#### **HEALTH PORTFOLIO**

## Additional Estimates 2016 - 2017, 1 March 2017

**Ref No:** SQ17-000381

**OUTCOME:** 4 - Individual Health Benefits

**Topic:** Life Saving Drugs Program

Type of Question: Written Question on Notice

**Senator:** Watt, Murray

## **Question:**

a) The new criteria does not reference PBAC at all – does this mean that PBAC has no role in assessing applications?

- b) If PBAC doesn't assess the applications, who does?
- c) Does this mean that that the "life-saving" component will be judged by a panel without the expert/medical knowledge of PBAC?
- d) Do you think this is appropriate given the lack of longitudinal data around rare diseases?
- e) What impact does the wording change for criteria number 4 have on reimbursement submissions that were already being considered for funding on the LSDP against the previous wording?

#### **Answer:**

a) The Pharmaceutical Benefits Advisory Committee (PBAC) does not have a role in assessing Life Saving Drugs Program (LSDP) applications. However, in order to make an LSDP application, a drug must have first been assessed by the PBAC as part of a Pharmaceutical Benefits Scheme (PBS) listing application – and the PBAC must have, as part of assessing that PBS listing application, accepted the medicine as clinically effective, but rejected it for PBS listing because it fails to meet the required cost effectiveness criteria under the *National Health Act 1953*.

### b) and c)

The Chief Medical Officer provides advice to the Minister about whether LSDP criteria are met, following an assessment of an application. In considering this advice, the Chief Medical Officer has regard to the PBAC's assessment of the medicine (for PBS listing) and can take advice from other experts and sources as necessary.

- d) The Chief Medical Officer has regard to the PBAC's earlier assessment of the medicine for PBS listing and can take advice from other experts and sources as necessary.
- e) There have been no changes to the operation of the Life Saving Drugs Program.