# Submission Template

**Pharmaceutical Benefits Advisory Committee (PBAC)**

**PD-1 and PD-L1 checkpoint inhibitor immunotherapies: options for subsidy consideration for multiple cancer types**

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| Cover sheetThis submission template should be used to provide comments on the Background paper relating to the PBAC consideration of PD-1 and PD-L1 checkpoint inhibitor immunotherapies: options for subsidy consideration for multiple cancer types  |
| Contact Details |
| **Company/Organisation represented:** |  |
| **Contact name:** |  |
| **Phone number:** |  |
| **Email:** |  |
| **Date of submission:** |  |
| **Category of submitting individual/organisation** | Are you (select one only)[ ] Patient[ ] Consumer organisation[ ] Pharmaceutical industry[ ] Healthcare Provider[ ] Professional organisation[ ] Researcher[ ] Government Body[ ] Other (please outline) - ………… |
| **Confidentiality and publishing of submissions** | Please note - all submissions received will be published on the PBS website at the conclusion of the public submission period, unless otherwise requested.Where submissions indicate commercial-in-confidence or sensitive personal information, this is redacted before publication.Please ensure any commercial –in-confidence or sensitive information is clearly marked. |
| Submission InstructionsSubmissions should be made by **5pm AEST on 29 June 2018**. The PBAC will not consider late submissions. Submissions should be lodged electronically, preferably in this template, in Microsoft Word or other text based formats, to the email address pbac@health.gov.au |

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| **PD-1 and PD-L1 checkpoint inhibitor immunotherapies: options for subsidy consideration for multiple cancer types** |
| General/overall comments Please note, comments that are beyond the scope of PD-1 and PD-L1 checkpoint inhibitor immunotherapies: options for subsidy consideration for multiple cancer types will not be considered |
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| Specific responses Please insert your comments against the consultation questions below.  |
| **Question 1** What do you/your organisation see as the potential advantages of the PBAC considering the PD-1 and PD-L1 checkpoint inhibitors for multi-tumour listings? |
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| **Question 2**What do you/your organisation see as the potential disadvantages of the PBAC considering the PD-1 and PD-L1 checkpoint inhibitors for multi-tumour listings? |
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| **Question 3**What is urgent unmet clinical need? How should it be established? For which patient groups?  |
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| **Question 4**What is the minimum level of evidence of effectiveness that you/your organisation think should be required before a PD-1 and PD-L1 checkpoint inhibitors is considered for subsidy for a particular kind of cancer? Why? |
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| **Question 5**Do you/your organisation think it is possible for the PBAC to be able extrapolate, or apply, the evidence of effectiveness of a checkpoint inhibitor in one kind of cancer to another kind of cancer, or from late stage cancer to early stage cancer? Why? How?  |
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| **Question 6**Do you/your organisation think it is possible for PBAC to satisfy itself that treatment with a PD-1 or PD-L1 checkpoint inhibitor is cost-effective without an economic model that is specific to that kind of cancer? How?* Is it possible to group different cancer types together based on particular characteristics that are similar, and construct a single model for the group?
* Are other approaches to establishing cost-effectiveness across cancer types possible? What are those approaches and how would they operate?
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| **Question 7**What do you/your organisation think is a reasonable subsidy price for Government to pay for a PD-1 or PD-L1 medicines for cancer types where the benefit is potentially very modest? |
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| **Question 8**Do you/your organisation think PD-1 and PD-L1 medicines should be made available to all patients whose cancers display a particular biomarker? Why? Which biomarker? |
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| **Question 9**Do you/your organisation think it is appropriate for the PBAC to extrapolate the evidence from one PD-1 or PD-L1 checkpoint inhibitor to other medicines in the same class(es). This could provide patients with more choice and give Government the opportunity to negotiate better subsidy prices by utilising the competition between sponsors of medicines. |
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| **Question 10**Do you/your organisation think that different evidentiary requirements are appropriate for rare cancers? How do you think cost-effectiveness should be established in this case?  |
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| **Question 11**Do you/your organisation think PBAC should set aside one of its meetings each year to consider only PD-1 or PD-L1 inhibitors for cancer? (This would mean no other submissions for other medicines, including other cancer medicines, or other diseases would be considered at that meeting.) |
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| **Question 12**If limited evidence is available at the time of subsidy of a PD-1 or PD-L1 inhibitor for a type of cancer, what do you/your organisation think should happen afterwards?* Should sponsors be required to collect more evidence?
* What should happen if the new evidence shows the medicine is less effective or has greater safety risks than expected?
* Should the medicine continue to be subsidised but at a price commensurate with its benefit? Should the sponsor be compelled to continue to make the medicine available even if it thinks the price is too low?
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| **Question 13****(For industry/clinical groups)** Clinical study information: (Please use the template provided for this information.)* In what indications has your organisation completed clinical trials with a PD-1 and PDL1 inhibitor? Please include both positive and negative studies.
* In what indications is your organisation currently conducting or planning to conduct clinical trials with PD-1 or PD-L1 inhibitors? If usual PBAC processes were to be followed, when would you expect to make an application for subsidy for these indications?
* How does your organisation decide which indications to study and which to prioritise for registration or subsidy?
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| **Question 14**Are there effective international models for multi-tumour subsidy that could be applied in Australia within the current regulatory framework? |
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| **Question 15****(For Industry)** What information can you provide regarding established international agreements for multi-tumour subsidy and how could these apply in the Australian regulatory context? |
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| **Question 16**Is there anything else you/your organisation would like to add? |
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