PBAC Outcomes

This document contains information regarding your application(s) considered by the Pharmaceutical Benefits Advisory Committee (PBAC) at its July 2025 meeting. By opening this document, you are confirming that you and your organisation will not publicise the PBAC outcome before publication of meeting outcomes on the PBS website on 22/08/2025, six weeks after the conclusion of the PBAC meeting.

The Secretariat will not respond to requests for further information about the outcomes of the meeting prior to ratified minutes being sent to sponsors.

The outcome for your application is as follows:

Drug Name	Trade Name	Indication	Application Type	Outcome
PEMBROLIZUMAB	Keytruda	Unresectable advanced and metastatic cancers	N/A	NOT RECOMMENDED

Note: Advice that a drug has been recommended by the PBAC should not be taken to mean that the drug was recommended exactly as was proposed in the application

Further information about the outcome(s) listed in the above table will be included in the ratified minutes.

Minutes:
In accordance with the PBAC Calendar published on the PBS website, the scheduled date for ratified minutes for positive recommendations to be sent to applicants is 01/08/2025. The scheduled date for the ratified minutes for all other recommendations to be sent to applicants is 15/08/2025**.**

Positive outcomes:
A document will be included in the Ratified minutes folder when the minutes for positive recommendations are shared with the applicant. This document will contain instructions for the next steps towards PBS listing, and a request regarding the provision of the minutes to the Australian Commission on Safety and Quality in Health Care for the purpose of developing RADAR publications.

Further information is available in the Procedure Guidance Section 8 Procedures for a positive recommendation to list www.pbs.gov.au/info/industry/listing/procedure-guidance/8-procedures-positive-recommendation-list/8-procedures-for-a-positive-recommendation-to-list

Not recommended outcomes:
All applicants with a 'not recommended' PBAC outcome are able to lodge a resubmission via the Standard Re-entry Pathway. Based on the PBAC's independent assessment of the level of additional information required and issues to be addressed before further PBAC consideration, the PBAC may have nominated an Early Resolution, Early Re-entry or Facilitated Resolution Pathway. Should the applicant not accept the PBAC nominated resubmission pathway, but still wish for further PBAC consideration, the Standard Re-entry Pathway applies. Further information is available in the Procedure Guidance under Section 9 Procedures for submissions not recommended www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-Procedures-for-submissions-not-recommended

Post-PBAC meeting
Applicants with a 'not recommended' PBAC outcome may request a meeting with the PBAC Chair to develop an understanding of the reasons for the PBAC decision. The PBAC Chair has the discretion to

accept requests for a post-PBAC meeting for positive recommendations. In these cases, it is expected that this meeting will provide the applicant with additional context and information on the recommendation to enable the applicant to proceed to a pricing pathway.

The PBAC Chair cannot change the recommendation of the PBAC.

Post-PBAC Meetings are scheduled to be held from 19/08/2025 to 20/08/2025**.** Requests for post-PBAC meetings must be lodged via the HPP using the correspondence category 'Post-committee meeting request' and must be received by **01/08/2025 08:00:00 AM (Canberra ACT time).** Please notify the HTA Support Unit if the meeting should be cancelled because you no longer have the requirement for a post-PBAC meeting after receiving your minutes. We are unable to accommodate late requests to add a meeting.

Further information is available in the Procedure Guidance under Section 7.1.4 Procedures for requesting a post-PBAC meeting with the PBAC Chair:
www.pbs.gov.au/info/industry/listing/procedure-guidance/7-post-pbac-decision-procedures-sponsors/7-1-notification-of-outcomes-of-pbac

Notice of Intent – resubmission pathways
The requirement for a Notice of Intent (prior notice) to be lodged by the respective nominated resubmission pathway deadline is prescribed by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022*. The Health Products Portal (HPP) is the approved method for lodging a Notice of Intent form, which is mandatory for all submissions lodged for PBAC consideration. A resubmission will not proceed to the PBAC if a Notice of Intent and full submission have not been submitted by 5pm AEDT on or by the due date (lodgement dates are available on the PBAC Calendar).

Further information is available at: www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-2-Intent-to-Apply_Resubmission-pathways

Lodging a submission for a resubmission pathway
Information regarding timelines for lodgement, documents required in a submission and confirmation of Early Re-entry or Early Resolution pathway considerations are available at www.pbs.gov.au/info/industry/listing/procedure-guidance/9-review-pbs-listings/9-3-Lodging-a-submission-for-a-resubmission-pathway

Guidance material
Guidance material is available to applicants who wish to make a submission to the PBAC. These documents include the *Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee* and *Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme*. Further information is available on the PBS website at: www.pbs.gov.au.

The Secretariat will not respond to requests for further information about the outcomes of the July meeting prior to ratified minutes being sent to sponsors.

s47E(c), s47F
A/g PBAC Secretary

Office of Health Technology Assessment
Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health, Diability and Ageing
E: PBAC@health.gov.au
GPO Box 9848, Canberra ACT 2601 (MDP 900)

s47E(c), s47F

From: s47E(c), s47F
Sent: Monday, 2 February 2026 5:26 PM
To: s47E(c), s47F
Cc: s47E(c), s47F
Subject: RE: KEYTRUDA Multi-Cancer Funding update [SEC=OFFICIAL]

Hi s47E(c), s47F below for clearance, thanks

1. The issues raised in the email below and if there is anything the department or minister's office can do to make the listing run faster?

Merck Sharp and Dohme (MSD) – pembrolizumab (Keytruda®)

- The Department met with MSD on 23 January 2026 to discuss next steps to progress the listing of pembrolizumab (Keytruda®) for the treatment of advanced or metastatic cancers, recommended at the December 2025 PBAC meeting.
- s47E(d)
- The PBAC recommended pembrolizumab be subject to the same pricing structure and join the Risk Sharing Arrangement (RSA) recommended for s22 broad listing in September 2025.
- s22
- Where an offer for a competitor product is being considered, the Department is not able to share the details of this process with another sponsor. As per standard practice, MSD will be provided those details (i.e. any RSA information) once s22 is listed.
- s47E(d)

s22

From: s47E(c), s47F @Health.gov.au>
Sent: Monday, 2 February 2026 10:33 AM
To: s47E(c), s47F @health.gov.au>
Cc: s47E(c), s47F @Health.gov.au>
Subject: FW: KEYTRUDA Multi-Cancer Funding update [SEC=OFFICIAL]

OFFICIAL

Hi s47E(c), s47F

Are you able to assist with the below? I've attached your previous input to the MO on s22 dated 13 January 2026.

Important
Requires AS clearance

Kindest,
s47E(c), s47F

OFFICIAL

From: s47E(c), s47F @Health.gov.au>
Sent: Monday, 2 February 2026 9:53 AM
To: s47E(c), s47F @Health.gov.au>
Subject: FW: KEYTRUDA Multi-Cancer Funding update [SEC=OFFICIAL]

OFFICIAL

Hi s47E(c), s47F

The Office is seeking advice on:

1. The issues raised in the email below and if there is anything the department or minister's office can do to make the listing run faster?
2. A status update on the progress of s22 to PBS listing.

Could you please assist?

Thanks,
s47E(c), s47F

OFFICIAL

OFFICIAL

From: s47F
Sent: Friday, 23 January 2026 4:02 PM
To: s47E(c), s47F @Health.gov.au>

Cc: s47F
Subject: KEYTRUDA Multi-Cancer Funding update

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Public

Hi s47E(c), s47F

Just providing a quick update on our meeting with the Department this afternoon.

s47G

As you can imagine, we're quite concerned by the prospect of it taking a year to convert a PBAC recommendation into a PBS listing – especially given it took three years to even get to a point of a PBAC recommendation and the high amount of advocacy we've seen from clinicians and patient organisations in support of the Multi-Cancer Funding arrangement.

It would be appreciated if you could discuss the matter with the Department to see what options might be available to avoid a one-year delay and ensure this is available to patients through the PBS as soon as possible.

Happy to chat next week.

Kind regards,

s47F

MSD.com

MSD

Australian Government
Department of Health, Disability and Ageing

Information Brief
MB25-001098
Version (1)
Date sent to MO: 15/07/2025

To: **Minister Butler**

cc: Minister Rae
Assistant Minister Kearney

Subject: **DEPARTMENT INITIATED BRIEF - OUTCOMES OF THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE MEETING 9-11 JULY 2025**

Comments:			
Contact Officer:	s47E(c), s47F	*Director, PBAC Assessment and Outcomes Section, Office of Health Technology Assessment*	*Ph:* s47E(c), s47F *Mobile:* s47E(c), s47F
Clearance Officer:	*Andrew Rintoul*	*Assistant Secretary, Office of Health Technology Assessment*	*Ph:* s47E(c), s47F *Mobile:* s47E(c), s47F

s22

s22

5. The PBAC considered four very high interest drugs at its July 2025 meeting:

s22

- Pembrolizumab – broad listing for advanced and metastatic cancer.

The outcomes of these items are set out at the start of **Attachment B**. s22

Background:

The PBAC meets three times per year, in March, July and November, to consider submissions relating to the PBS and National Immunisation Program (NIP). Under the *National Health Act 1953* (Act), the Australian Government cannot list a medicine on the PBS or include a vaccine on the NIP unless it has first been recommended by the PBAC. The PBAC is required by the Act to *"give consideration to the effectiveness and cost of therapy with that of alternative therapies, whether or not involving the use of other drugs or preparations."* (Section 101 (3A) of the Act).

The PBAC also holds three intracycle meetings per year, in May, September and December, to consider matters related to the administration of the PBS and deferred items from previous meetings.

Next Steps: The next steps to progress the July 2025 recommendations are:

i. 16 July 2025 – sponsors receive brief advice via the Health Products Portal about the PBAC outcome (following confirmation that sponsors will not disclose the outcome prior to its publication on the PBS website)
ii. 1 August 2025 – written minutes provided to sponsors for positive recommendations to enable pricing negotiations, risk sharing negotiations and other pre-listing activities
iii. 15 August 2025 – written minutes provided to sponsors for all other recommendations
iv. 19-20 August 2025 – the PBAC Chair will meet with the sponsors who request a post-PBAC meeting to discuss the PBAC outcomes in more detail
v. 22 August 2025 – the November 2024 PBAC outcomes published on the PBS website (the office will be notified prior to publication)
vi. 31 October 2025 – Public Summary Documents published on the PBS website for positive recommendations and subsequent not recommended items (the office will be notified prior to publication)

vii. 14 November 2025 – Public Summary Documents published on the PBS website for first time not recommended items and deferrals.

Attachments:

A. July 2025 PBAC meeting outcomes
B. July 2025 recommendations likely to attract media attention
C. Category and pathway descriptions
D. Further details about the donanemab submission

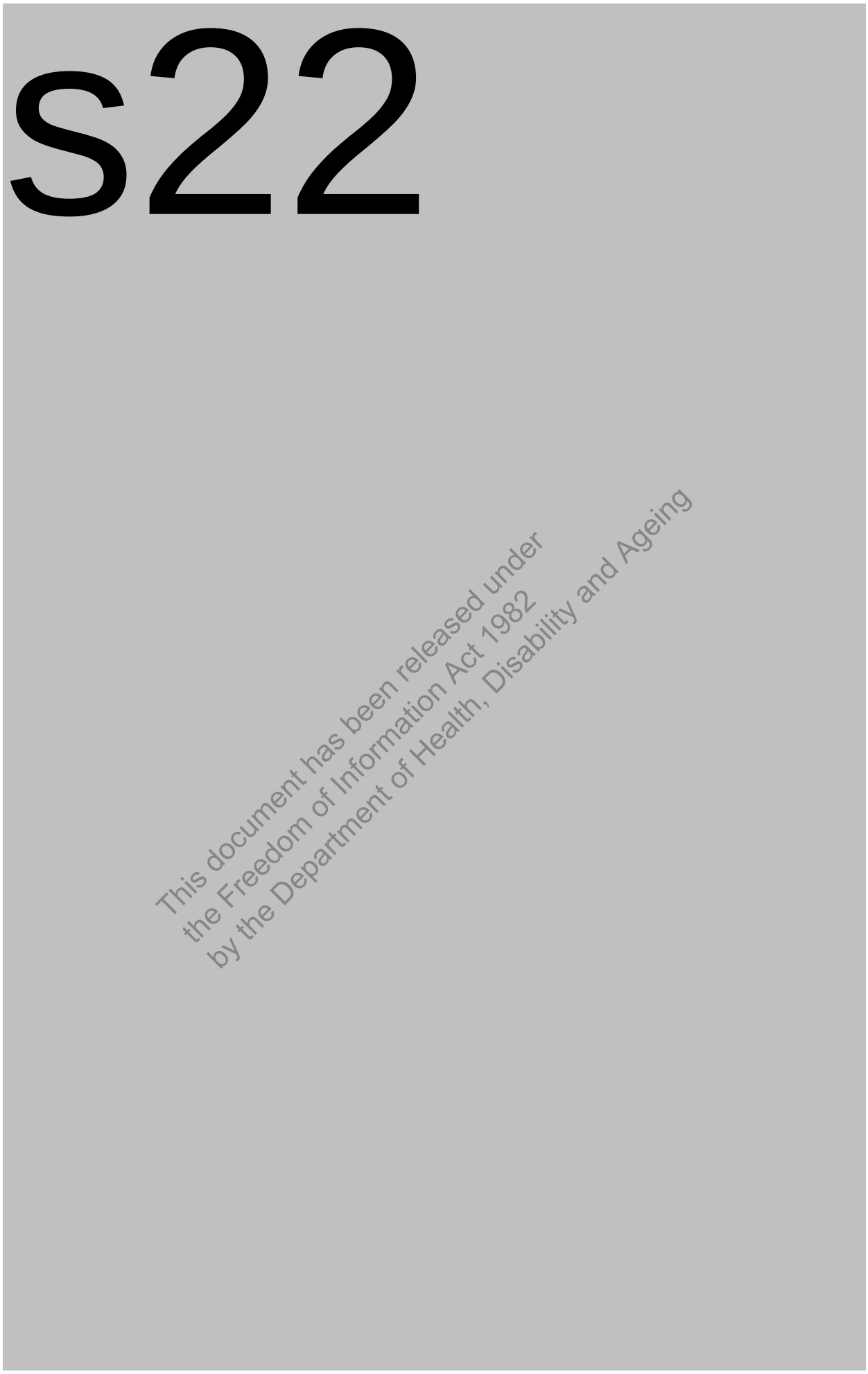
Attachment A

July 2025 PBAC Meeting Outcomes

Recommended

Item	Purpose

s22


s22
This document has been released under
the Freedom of Information Act 1982
by the Department of Health, Disability and Ageing

s22

Not recommended

Item	Purpose
s22	
Pembrolizumab (Keytruda®)	To consider a proposal for an expanded listing to facilitate
s22	

Deferred

Item	Purpose
s22	

s22

ATTACHMENT B

JULY 2025 PBAC DECISIONS LIKELY TO ATTRACT STAKEHOLDER / MEDIA ATTENTION

s22

s22

PD-1 inhibitor drugs for Advanced and metastatic cancer (broad/ tumour agnostic listing)

s22

The PBAC **did not recommend** the proposal for a broad listing for unresectable advanced and metastatic cancer for **pembrolizumab**. The PBAC noted the proposal was limited to TGA registered indications for pembrolizumab and would not facilitate access for some patient groups in which there is an unmet need, such as rare cancers. s38

s22

s22

s22

s22

s22

s22

s22

s22

ATTACHMENT C

Category and pathway descriptions

Pricing Pathways

There are five different pricing pathways to progress a positive PBAC recommendation. Further information is available in the procedure guidance at: www.pbs.gov.au/info/industry/listing/procedure-guidance/8-procedures-positive-recommendation-list/8-1-price-agreement

Pricing Pathway A is a facilitated pathway. A Case Manager will be assigned where the applicant has accepted the PBAC's recommendation for Pricing Pathway A. It is the highest cost pricing pathway. If the PBAC has recommended Pricing Pathway A for a submission, the applicant will either accept the PBAC's Pricing Pathway A recommendation or nominate another pricing pathway via the Notice of Intent for Pricing form.

Pricing Pathway A requires the PBAC to recommend that it is appropriate for a submission to follow this pathway. All other pricing pathways are determined based on the listing arrangements required.

Pricing Pathway A can apply for submissions where the PBAC considers that:

- the medicine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies; and
- the medicine addresses a high and urgent unmet clinical need; and
- it would be in the public interest for the submission to be recommended to follow this pathway

In relation to the public interest component of the criteria, the PBAC will have regard to whether it is likely that the interests of the Australian public will be advanced by the recommendation being progressed via Pricing Pathway A, noting that the submission must also meet the first two criteria.

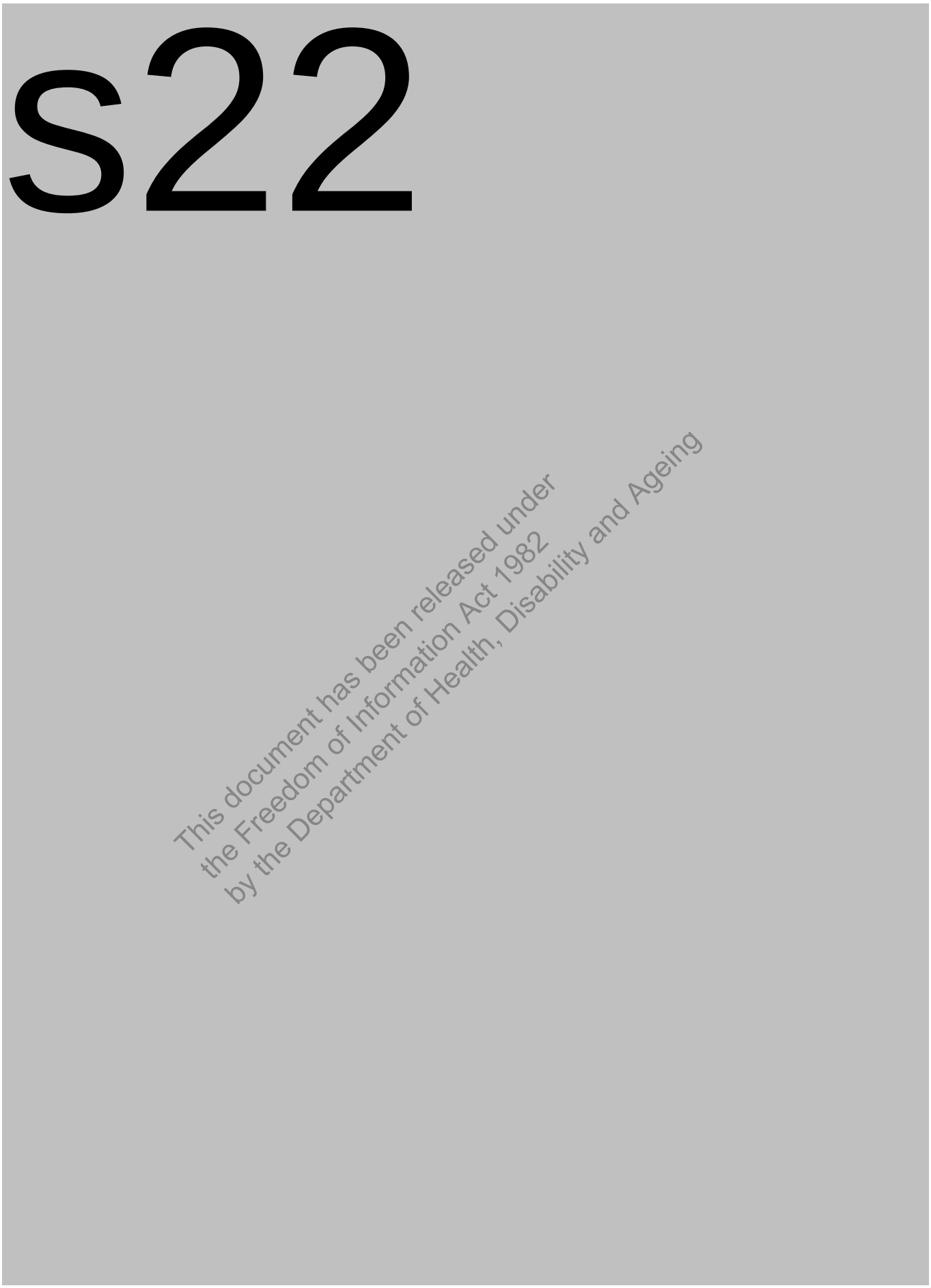
Submission category types

Category 1	A request for PBS or NIP listing of one or more of the following: • A first in class medicine or vaccine, and/or a medicine or vaccine for a new population. OR • A drug with a codependent technology that requires an integrated codependent submission to the PBAC and MSAC. OR • A drug or designated vaccine with a TGA Provisional determination related to the proposed population.
Category 2	A request for PBS or NIP listing of a new medicine or new vaccine, a new indication of a currently listed medicine or vaccine, or to make material changes to a currently listed indication and do not meet the criteria for a Category 1 submission.
Category 3	Requests to change existing listings that do not change the population or cost-effectiveness of the medicine or vaccine that do not meet the criteria for a Category 4 submission.
Category 4	A request for one or more of the following: • Listing of a new pharmaceutical item of a listed medicine. • Consideration as an exempt item (Exempt item as per subsection 84AH of the *National Health Act 1953*). • Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing. • A change/new manner of administration of a listed medicine. • A change to the maximum quantity and/or number of repeats of a listed medicine. • A change or addition to the prescriber type(s) of a listed medicine.
Committee Secretariat	Application is not in Categories 1, 2, 3 or 4 and requests for one or more of the following: • New or varied listed drugs, medicinal preparations and designated vaccines that pose no greater risk • Pharmaceutical benefits that can no longer be supplied early • New brand of glucose indicator pharmaceutical item.

Resubmission pathways

There are four different resubmission pathways available to applicants following a 'not recommended' PBAC outcome. Resubmission pathways are not available for submissions that receive a positive recommendation from the PBAC. The resubmission pathways are classified into the following categories:	
Standard re-entry	The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where: • an applicant chooses not to accept the PBAC nominated resubmission pathway; or • an Early Re-entry or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or • an applicant decides to lodge later than the allowable timelines for the other pathways.
Early re-entry pathway	An Early Re-entry Pathway may be nominated by the PBAC where the PBAC considers that the remaining issues could be easily resolved and the medicine or vaccine does not represent High Added Therapeutic Value (HATV) for the proposed population. Applicants who accept this pathway are eligible for PBAC consideration at the immediate next meeting.
Early resolution pathway	For medicines or vaccines deemed by the PBAC to represent HATV AND where the PBAC considers that the remaining issues could be easily resolved, including when: • new clinical study data requiring evaluation is not considered necessary by the PBAC to support new clinical claims to be made in the resubmission; and • a revised model structure or input variable changes (beyond those specified by the PBAC) are not necessary to support any new economic claims, or to estimate the utilisation and financial impacts to be made in the resubmission. Applicants who accept this pathway are eligible for PBAC consideration out-of-session (before the main meeting), unless the department, in consultation with the PBAC Chair, identifies an unexpected issue such that the resubmission needs consideration at the next main PBAC meeting.
Facilitated resolution pathway	A Facilitated Resolution Pathway may be nominated by the PBAC where the PBAC considers the issues for resolution could be explored through a workshop AND where the medicine or vaccine meets the HATV criteria. Applicants who accept this pathway are eligible for a solution-focussed workshop with one or more members of the PBAC. The workshop agenda will be based on the issues for resolution outlined in the PBAC Minutes. This can be further clarified during the post-PBAC meeting with the Chair.

ATTACHMENT D



s22

Minister	**Minister Butler**
PDR Number	**MB25-001098**
Subject	**Dept Initiated Info Brief | Outcomes of the Pharmaceutical Benefits Advisory Committee meeting 9-11 July 2025**
Contact Officer	s47E(c), s47F
Clearance Officer	Andrew Rintoul s47E(c), s47F
Division/Branch	|Health Resourcing| Technology Assessment & Access
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Australian Government
Department of Health, Disability and Ageing

Ministerial Information Request
MB25-001472
Version (1)
Date sent to MO: 15/08/2025

To: **Minister Butler**

Subject/Issue: **MIR - PBAC Decision - Multi-Cancer Funding proposal for KEYTRUDA**

Comments:			
Contact Officer:	s47E(c), s47F	*Director* *PBAC Governance Section*	Ph: s47E(c), s47F
Clearance Officer:	Daniel Chaston	*Assistant Secretary (A/g),* *Pharmaceutical Assessment Branch,* *Technology Assessment and Access Division*	Ph: s47E(c), s47F Mobile s47E(c), s47F

Response:

***** IN CONFIDENCE*****

Pembrolizumab:

- At its July 2025 meeting the PBAC considered and did not recommend a proposal from Merck Sharp & Dohme (Australia) (MSD) for its drug, pembrolizumab (Keytruda®), for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.
- The PBAC noted the pembrolizumab proposal was limited to TGA registered indications for pembrolizumab and would not facilitate access for some patient groups in which there is an unmet need, such as rare cancers.
- The PBAC noted it was access for this area of clinical need that was one of the initial driving factors behind the broad listing proposals for PD-L(1) inhibitors.
- s38

- s38

- MSD has sought a post-PBAC meeting with the PBAC Chair for the item which will occur on 20 August 2025. Members of the PBAC Secretariat will also attend the meeting.
- The purpose of post-PBAC meetings is to allow applicants to develop an understanding of the reasons for the PBAC decision and understand what the appropriate path forward for a potential resubmission might be.
- MSD received the ratified minutes (**Attachment A**) for their consideration on 15 August 2025.
- The outcomes from the July 2025 PBAC meeting will be published on the PBS website on Friday 22 August 2025.
- The PBAC acknowledges the collaborative efforts of the sponsor and the department in preparing the proposal and the significant work that has been undertaken to date. In the minutes, the PBAC encouraged the sponsor to continue to work with the department and to consider whether a revised set of financial estimates and pricing proposal that addressed the issues raised in this consideration could be brought forward for consideration at a future meeting.

s22

General

- s47E(d)
- s47E(d)

Standard words:

- The Government requires the advice of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body, about the listing of medicines on the PBS and cannot list a medicine on the PBS unless the PBAC recommends its listing.
- Similarly the Government relies on the advice of the PBAC for a change to the circumstances of PBS listing to be made.
- The Government does not interfere with the PBAC's considerations or process to develop recommendations to Government.
- The PBAC is an independent and expert body, comprising doctors, health professionals, health economists and consumer representatives.
- An unfavourable PBAC outcome does not necessarily represent the PBAC's final views on the merits of a medicine.

Key Points:

- The department worked with both sponsors to prepare a submission that addressed the PBAC's previous advice on the parameters for a broad listing proposal.
- s47E(d)
-
-

Background:

- At its December 2023 intracycle meeting, the PBAC considered whether it would be appropriate to amend the circumstances under which Keytruda® is available on the PBS to subsidise use in all of the indications registered for the drug. The PBAC recommended that MSD, the pharmaceutical company responsible for the supply of Keytruda® in Australia, consult with the department further regarding the restriction, the price at which Keytruda® is likely to be cost-effective, the financial forecasts and parameters for a RSA.
- At its September 2024 intracycle meeting, the PBAC considered, and deferred making a decision on, updated proposals for both pembrolizumab and s22 . The PBAC provided advice on the necessary parameters for a broad listing proposal and asked the companies provide an updated proposal that aligned with this advice.
- s47E(d)

Consultations: This matter is within TAAD remit, broader consultation was not required.

Australian Government
Department of Health, Disability and Ageing

Information Brief
MB25-003020
Version (1)
Date sent to MO: 16 December 2025

To: Minister Butler

Subject: OUTCOMES OF THE PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE INTRACYCLE MEETING 10 DECEMBER 2025

Comments:			
Contact Officer:	s47E(c), s47F	*Director, PBAC Assessment and Outcomes Section, Pharmaceutical Assessment Branch*	*Ph:* s47E(c), s47F *Mobile:* s47E(c), s47F
Clearance Officer:	*Andrew Rintoul*	*Assistant Secretary, Pharmaceutical Assessment Branch, Technology Assess and Assessment Division*	*Ph:* s47E(c), s47F *Mobile:* s47E(c), s47F

Key Issues:

s22

3. This included recommendations for new and expanded access to treatments or prevention for Australians for the following conditions:

s22

b. **Advanced and metastatic cancer:** the PBAC recommended a broad (multi-indication) listing for pembrolizumab.

s22

4. A summary of the PBAC's advice for matters likely to attract stakeholder/media attention is provided at **Attachment B**.

Background:
The PBAC meets three times per year, in March, July and November, to consider submissions relating to the PBS and National Immunisation Program (NIP). Under the *National Health Act 1953* (Act), the Australian Government cannot list a medicine on the PBS or include a vaccine on the NIP unless recommended by the PBAC. The PBAC is required by section 101(3) of the Act to consider the effectiveness and cost of therapy compared with alternative therapies.

The PBAC also holds intracycle meetings in May, September and December, to consider matters related to the administration of the PBS and deferred items from previous meetings.

Next Steps: The next steps to progress the December 2025 recommendations are:

i. **17 December 2025** – sponsors receive brief advice via the Health Products Portal about the PBAC outcome (following confirmation that sponsors will not disclose the outcome prior to its publication on the PBS website)
ii. **9 January 2026** – the ratified minutes of submissions that received positive recommendations are provided to sponsors to enable pricing negotiations, risk sharing negotiations and other pre-listing activities
iii. **23 January 2026** – all other ratified minutes are provided to sponsors

iv. **27-28 January 2026** – the PBAC Chair will meet with sponsors who request a post-PBAC meeting to discuss the PBAC outcomes in more detail
v. **30 January 2026** – the outcomes are published on the PBS website (the office will be notified prior to publication)
vi. **10 April 2026** – the Public Summary Documents will be published on the PBS website (the office will be notified prior to publication)

Attachments:

A. December 2025 PBAC meeting outcomes
B. December 2025 recommendations likely to attract media attention
C. Category and pathway descriptions

Attachment A

December 2025 PBAC Meeting Outcomes

Recommended

Item	Purpose
s22	
PEMBROLIZUMAB (Keytruda®)	To consider a revised proposal for a broad (multi-cancer) listing for pembrolizumab for advanced and metastatic cancers.
s22	

Advice provided

Item	Purpose
s22	

Item	Purpose
s22	

Attachment B

DECEMBER PBAC DECISIONS LIKELY TO ATTRACT MEDIA ATTENTION

Recommended outcomes:

s22

Unresectable advanced and metastatic cancer (broad / tumour agnostic listing)

The PBAC **recommended** a broad (multi-indication) listing for pembrolizumab for use in advanced and metastatic cancers based on the revised proposal presented by the sponsor.

s38

The PBAC asked that, should the broad listing for pembrolizumab proceed, the sponsor work with the clinical groups and with the sponsor of s22 in developing and providing consistent and informative educational resources for prescribers and patient groups.

s22

s22

s22

s22

s22

Minister	**Minister Butler**
PDR Number	**MB25-000392**
Subject	**Outcomes of the Pharmaceutical Benefits Advisory Committee meeting 5 September 2025**
Contact Officer	s47E(c), s47F
Clearance Officer	Andrew Rintoul s47E(c), s47F
Division/Branch	|Health Resourcing| Technology Assessment & Access
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Web outcome for July 2025 considerations of broad (multi-indication) listing proposals for PD-L(1) inhibitors.

Please note, these are under embargo until published on the PBS website on 22 August 2025

NIVOLUMAB Injection concentrate for I.V. infusion 40 mg in 4 mL Injection concentrate for I.V. infusion 100 mg in 10 mL Opdivo® IPILIMUMAB Injection concentrate for I.V. infusion 50 mg in 10 mL Injection concentrate for I.V. infusion 200 mg in 40 mL Yervoy® BRISTOL-MYERS SQUIBB AUSTRALIA PTY LTD Category 2 (Change to existing listing	Unresectable advanced and metastatic cancer	To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.	Deferred	The PBAC deferred making a recommendation for an expanded listing of nivolumab and ipilimumab for a multi-indication (broad) listing in unresectable advanced or metastatic cancers. The PBAC considered the most recent proposal from the sponsor had met the majority of its expectations to support a broad listing but considered further discussions were required to finalise the requirements of the Risk Sharing Arrangement (RSA) and financial estimates to ensure the price at which the drugs would be supplied would be cost-effective in all treatment scenarios covered by the listing and the financial risk was acceptably shared between the sponsor and the Commonwealth. The PBAC welcomed the approach of the proposal which would provide clinician discretion to use the medicines in an evidence-based manner and provide access to patient groups with rare cancers where there was evidence of benefit, but for which it was unlikely that a submission for PBS listing for the specific indications would be made. The PBAC noted that, should a broad listing proceed, it would be necessary for the sponsor and clinical community to ensure utilisation of the listing occurred consistent with the intent of the listing. That is, that the medicines would be supplied under the PBS only for indications for which there was evidence to support a reasonable expectation of efficacy and a positive benefit to risk balance for that condition. As such, the PBAC welcomed the sponsor's intention to develop supporting prescriber educational and evidence-based resources to support the listing if it were to be recommended and implemented. The PBAC asked that the sponsor consider the proposed amendments to the financial estimates and RSA structure and provide a revised proposal aligned with these for consideration at the next available opportunity.

Web outcome for July 2025 considerations of broad (multi-indication) listing proposals for PD-L(1) inhibitors.

Please note, these are under embargo until published on the PBS website on 22 August 2025

PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda® MERCK SHARP & DOHME (AUSTRALIA) PTY LTD Internal submission Change to existing listing	Unresectable advanced and metastatic cancer	To consider a proposal for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.	Not recommended	The PBAC did not recommend the proposal for a multi-indication (broad) listing for pembrolizumab in advanced or metastatic cancers. The PBAC considered the proposal for the broad listing did not establish a reliable basis for the financial estimates, which also raised significant uncertainty in the ability to achieve a cost-effective listing, given the complex pricing and Risk Sharing Arrangement (RSA) structure proposed. The PBAC considered the prices proposed for each of the extended circumstances of use—including the additional indications, extended time on treatment, and retreatment—to be too high, and concluded that a further price discount would be required to ensure cost-effectiveness. The PBAC noted the proposal was restricted to the indications for which pembrolizumab was registered with the Therapeutic Goods Administration and, as such, would not provide access to some patient groups in which there is a significant unmet clinical need, such as rare cancers. The PBAC noted a regulatory and subsequent submission for subsidy was unlikely to be made for these patient groups and recalled it was access for this area of clinical need that was one of the initial driving factors behind the broad listing proposals for PD-L(1) inhibitors. The PBAC considered it was important that any broad listing proposal was paired with consideration of this area of unmet need, either as part of the proposal or in parallel with it. The PBAC acknowledged the collaborative efforts of the sponsor and Department in preparing the proposal and the significant work that had been undertaken to date. The PBAC encouraged the sponsor to continue to work with the Department and to consider whether a revised set of financial estimates and pricing proposal that addressed the issues raised in this consideration could be brought forward for consideration at a future meeting.

s47E(c), s47F

From: s47E(c), s47F
Sent: Tuesday, 25 February 2025 9:12 AM
To: s47E(c), s47F ; RINTOUL, Andrew; s47E(c), s47F
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL:Sensitive]

I agree, it is hard to commit to timeframes until there is something in front of us. I think at this stage March would be unlikely – perhaps we can add to Friday catch up with s47E(c), s47F and confirm whethe provided a response? I think key message is for them to get us a proposal and we'll work to find the earliest sible opportunity for consideration (which I expect will be May/July at this stage as I don't think this type of paper can be managed OOS).

Kind regards,

s47E(c), s47F

From: s47E(c), s47F
Sent: Tuesday, 25 February 2025 9:57 AM
To: RINTOUL, Andrew ; s47E(c), s47F
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL:Sensitive]

Hi Andrew,

Will defer to OHTA and PBAC to reply re: timing of consideration of any submission. I'd guess it's a bit difficult to gauge timeframes without seeing a submission to estimate how much work will be required by the Department to support the PBAC's review. And noting March already being at capacity.

Cheers,
s47E(c), s47F

From: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>
Sent: Monday, 24 February 2025 2:32 PM
To: s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: FW: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL:Sensitive]

Hi All,
Was this something I was supposed to respond to and didn't ie 14th Feb email.

Assuming where we are with s22 MSD would not be disadvantaged by not going to March but need to be consistent with both.

Kind regards

Andrew

Andrew Rintoul (he/him)
Assistant Secretary

Office of Health Technology Assessment | Technology Assessment and Access Division
Australian Government Department of Health and Aged Care
T: +61 2 s47E(c), s47F E: andrew.rintoul@health.gov.au
Location: Yaradhang 9.N.101

Executive Assistant | s47E(c), s47F @health.gov.au

PO Box 9848, Canberra ACT 2601, Australia
The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s47E(c), s47F @health.gov.au>
Sent: Monday, 24 February 2025 1:37 PM
To: RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>
Subject: FW: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Thoughts?

From: s47F
Sent: Monday, 24 February 2025 1:30 PM
To: s47E(c), s47F @health.gov.au>
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Confidential

Hi s47E(c), s47F

I was wondering if you've had a chance to discuss this further with the relevant people and have formed a view as to whether it's possible for a revised proposal to be considered by the PBAC in March?

s47G

Appreciate your guidance.

Kind regards

s47F

From: s47F
Sent: Friday, February 14, 2025 2:09 PM
To: s47E(c), s47F @health.gov.au>; s47F
s47E(c), s47F @health.gov.au>
Cc: s47F
RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; RICHARDSON, Rebecca <Rebecca.Richardson@health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Hi s47E(c), s47F

Thank you for providing the Department's comments.

s47G With your responses below in mind, we will now work on a revised proposal. The proposal will outline MSD's proposed approach to restrictions and pricing for advanced and metastatic indications with current or future TGA approval. This will build upon previous submissions that the PBAC and Department have already considered, with refinements based on our recent discussions.

We acknowledge your comments about the importance of access for patients with rare cancers and will ensure this is included in the proposal.

Based on your responses, we will work on the assumption that some of the issues around the Deeds can be resolved by the Department and MSD following a PBAC recommendation.

s47F , s47E(c), s47F noting the urgency to resolve this work, which was mentioned by you both in December, we would like to prioritise this and ensure a submission can be considered by the PBAC at the March meeting. What do we need to do to ensure this can be considered by the PBAC in March?

Your prompt guidance would be appreciated so we can progress this work and gain internal alignment with Global colleagues.

Kind regards

s47F

From: s47E(c), s47F @health.gov.au>
Sent: Tuesday, February 11, 2025 9:37 AM
To: s47F
Cc: s47F RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; RICHARDSON, Rebecca <Rebecca.Richardson@health.gov.au>; s47F ; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Confidential

EXTERNAL EMAIL– Use caution with any links or file attachments.
Hi s47F

Please see below the Department's comments in relation to MSD's questions. Please note this is provided without prejudice and is non-binding.

s38

S38

Kind regards,

s47E(c), s47F
Director

PBS Pricing and Managed Access Section

Technology Assessment and Access Division | Health Resourcing Group
Pricing and PBS Policy Branch
Australian Government Department of Health and Aged Care
T: 02 s47E(c), s47F | E: s47E(c), s47F @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

From: s47F
Sent: Monday, 10 February 2025 11:29 AM
To: s47E(c), s47F @health.gov.au>
Cc: s47F
RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; RICHARDSON, Rebecca <Rebecca.Richardson@health.gov.au>; s47F
s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Confidential

Hi s47E(c), s47F

I just wanted to follow up on the Department's response. Do you have an updated timeframe?

I also wanted to let you know that s47F and I will be in Canberra on Thursday for another meeting at the Department of Health.

If it's convenient to meet in person to discuss this topic while we're there please let me know.

Kind regards

s47F

From: s47E(c), s47F @health.gov.au>
Sent: Thursday, January 30, 2025 3:02 PM
To: s47F
Cc: s47F
RINTOUL, Andrew <Andrew.Rintoul@health.gov.au>; RICHARDSON, Rebecca <Rebecca.Richardson@health.gov.au>; s47F
; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Confidential] MSD response - expanded listing for pembrolizumab [SEC=OFFICIAL]

Some people who received this message don't often get email from s47E(c), s47F @health.gov.au. Learn why this is important

Confidential

EXTERNAL EMAIL– Use caution with any links or file attachments.
Hi s47F

Thanks for your patience while we consider MSD's queries. Just an update that we are working to provide a response next week.

Kind regards,

s47E(c), s47F
Director

PBS Pricing and Managed Access Section

Technology Assessment and Access Division | Health Resourcing Group
Pricing and PBS Policy Branch
Australian Government Department of Health and Aged Care
T: 02 5132 s47E(c), s47F @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

From: s47F
Sent: Friday, 20 December 2024 12:03 PM
To: s47F s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Cc: s47F
Subject: [Confidential] MSD response - expanded listing for pembrolizumab

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Confidential

Hi all,

Thank you for making the time to meet with us on 9 December.

MSD remains committed to working on an arrangement that would facilitate appropriate and timely access to pembrolizumab for Australian patients, and we appreciate the ongoing close collaboration with the PBAC and Department.

S38

s38

We look forward to connecting again early in the new year. Most of the MSD team is back to work from the 6th of January and would be happy to receive your written feedback or arrange another meeting.

s22

Wishing you a happy and restful holiday period.

Kind regards

s47F

Today MSD is a global healthcare leader working to help the world be well. MSD is a tradename of Merck & Co., Inc., Rahway, NJ., U.S.A. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.msd.com

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s47E(c), s47F

From: s47E(c), s47F
Sent: Wednesday, 16 April 2025 10:18 AM
To: s47E(c), s47F
Cc: s47E(c), s47F
Subject: FW: [Confidential] Meeting notes - Multi-indication proposal pembrolizumab [SEC=OFFICIAL]
Attachments: MSD_DoH_Meeting Notes_09APR2025_circ.docx

Hi s47E(c), s47F ,

FYI

Thanks,
s47E(c), s47F

From: s47F
Sent: Tuesday, 15 April 2025 8:07 PM
To: s47E(c), s47F
Cc: s47F
Subject: [Confidential] Meeting notes - Multi-indication proposal pembrolizumab

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Confidential

Hi all,

Thanks again for your time last week.

Given the tight timeframe we're working towards for the submission, it was helpful to discuss the level of information needed and agree on the areas to prioritise.

I've summarised the approach we discussed and captured a few next steps in the attached document.

Please let us know if there's anything we've missed or captured incorrectly.

As mentioned, I'll be in Canberra next week. Would it be possible to organise another meeting on Tue 22 April after 12pm or Wed 23 April at 9am or 10am?

I'm hoping to bring some draft spreadsheets and make sure we're on the right track in terms of the structure and information included.

s47F

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s47E(c), s47F

From: s47E(c), s47F
Sent: Monday, 19 May 2025 10:23 AM
To: s47E(c), s47F
Subject: Fw: [Confidential] RE: Pembrolizumab broad listing - July 2025 resubmission
Attachments: MSD_Pembrolizumab_Broad listing_Resubmission_16MAY2025_circ.docx; Pembro_Utilisation_Cost_Model_18MAY2025_circ.xlsx

---

From: s47F
Sent: 18 May 2025 23:22
To: s47E(c), s47F ; PBAC
Cc: s47F
Subject: [Confidential] RE: Pembrolizumab broad listing - July 2025 resubmission

Confidential

Hi s47E(c), s47F
Apologies, we noticed a minor error in the Excel. Please use the Excel attached to this email, dated 18 May.
As the error related to a published price (Sheet 18, Row 60) it wasn't part of the write up, so there has been no change to the Word document. I've just re-attached for convenience.

s47F

From: s47F
Sent: Friday, 16 May 2025 11:53 PM
To: s47E(c), s47F ; PBAC
Cc: s47F
Subject: Pembrolizumab broad listing - July 2025 resubmission

Dear s47E(c), s47F
Please find attached our submission requesting a broad and simplified listing for pembrolizumab (KEYTRUDA) for the PBAC's consideration at the July 2025 meeting.
The UCM is also attached. As discussed, please let us know if any changes need to be made to patient number estimates to align with previous PBAC decisions. We are willing to turn around any changes quickly, including updating the submission document, if required.
Thank you for your collaboration on this proposal.
Kind regards

s47F

s47F

msd-australia.com.au

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s47E(c), s47F

From: s47E(c), s47F
Sent: Friday, 23 May 2025 4:21 PM
To: s47F ; s47E(c), s47F ; s47F (Sydney LHD)
Cc: s47E(c), s47F ; PBAC
Subject: pembro and s22 broad listing proposals
Attachments: s22 ; MSD_Pembrolizumab_Broad listing_Resubmission_16MAY2025_circ.docx

Categories: Internal Evaluation Team

Hi all

Attached are new broad listing proposals from s22 and MSD, following advice from the PBAC in December 2023, a workshop with the Chair in December 2024, and further engagement between the sponsors and the Secretariat. Providing these for your information before the next July agenda upload. Spreadsheets/attachments/references will be available in agenda upload, but please reach out if you require something before then.

The general approach is a focus on advanced metastatic unresectable, allowing retreatment and use beyond 2 years.

s47E(d)

The department will prepare an overview for review and response from the sponsors prior to consideration at July PBAC. The item is not yet published on the July PBAC agenda on the website, but we aim to update the agenda next week.

Cheers

s47E(c), s47F
Director – PBAC Governance
Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government Department of Health, Disability and Ageing
T: +61 2 s47E(c), s47F @health.gov.au
This email comes to you from Ngunawal Country
PO Box 9848, Canberra ACT 2601, Australia
The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

s47E(c), s47F

From: s47E(c), s47F
Sent: Wednesday, 2 July 2025 2:36 PM
To: s47F
Cc: s47E(c), s47F; PBAC Members; s47E(c), s47F
Subject: RE: Broad Listing Proposal Documents - s22 6.15 s22 Pembro [SEC=OFFICIAL]
Attachments: s22 6.15 Summary and Comparison Overview.docx

Hi both,

We have compiled a high level summary and comparison of the two proposals, as well as comments on the pre-PBAC responses in the attached. If you are comfortable, I will also upload for the committee or can make changes as requested prior to that.

s47E(d)

Kind regards,

s47E(c), s47F

From: s47E(c), s47F
Sent: Monday, 30 June 2025 1:30 PM
To: s47F
Cc: s47E(c), s47F ; PBAC Members ; s47E(c), s47F
Subject: Broad Listing Proposal Documents - s22 6.15 s22 Pembro [SEC=OFFICIAL]

Hi s47F ,

As these are running a little bit out of sync with the standard submissions, I wanted to update you to let you know the submission overviews for these were uploaded to HPP last week and I have today added the consumer comments and pre-PBAC responses to the relevant HPP folders.

We are also preparing a high-level comparison paper of the two proposals and pre-PBAC responses and will aim to share this by the end of the week. Also happy to make time to discuss if that would be helpful.

Kind Regards,

s47E(c), s47F

Assistant Director – PBAC Governance Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health, Disability and Ageing

T: 02 s47E(c), s47F @health.gov.au

Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia

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s47E(c), s47F

From: s47E(c), s47F
Sent: Thursday, 21 August 2025 4:48 PM
To: s47E(c), s47F; s47F
Cc: s47E(c), s47F
Subject: Broad listing outcome talking points [SEC=OFFICIAL]
Attachments: Web outcome for July 2025 considerations of broad (multi-indication) listing proposals for PD-L(1) inhibitors.docx

Hi s47E(c), s47F,

We put together some general talking points about the web outcomes for the PD-L(1) broad listing proposals (attached) which will be published tomorrow afternoon in case you field any calls about them. Until the PSD's go up there is not much additional to the web outcome that we would generally share so they are fairly high level.

s22

Talking Points: Outcomes for broad (multi-indication) listing proposals for PD-L(1) inhibitors (pembrolizumab and s22)

- At its July 2025 meeting the PBAC considered a proposal from Merck Sharp & Dohme (Australia) (MSD) for its drug, pembrolizumab (Keytruda®), for an expanded listing to facilitate broad access for unresectable advanced and metastatic cancer.
- s22
- The outcomes of these considerations were published on the PBS website on 22 August 2025.
- Public Summary Documents, which provide specific detail on the PBAC's consideration, will be published for these items on 14 November 2025.

s22

Pembrolizumab

- The PBAC did not recommend the proposal for a multi-indication (broad) listing for pembrolizumab in advanced or metastatic cancers.
- s47E(d)
- The PBAC noted the proposal was restricted to the indications for which pembrolizumab was registered with the Therapeutic Goods Administration and, as such, would not provide access to some patient groups in which there is a significant unmet clinical need, such as rare cancers.
- An unfavourable PBAC outcome does not necessarily represent the PBAC's final views on the merits of a medicine.
- The PBAC's decision for pembrolizumab was in relation to the specific proposal put forward by the sponsor.

- The PBAC has invited the sponsor to provide an updated proposal addressing the issues raised for its consideration at a future meeting.

Kind Regards,

s47E(c), s47F

Assistant Director – PBAC Governance Section

Office of Health Technology Assessment
Technology Assessment and Access Division | Health Resourcing Group
Australian Government, Department of Health, Disability and Ageing

T: 02 s47E(c), s47F @health.gov.au

Location: Sirius Building
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health, Disability and Ageing acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

s47E(c), s47F

From: s47E(c), s47F
Sent: Friday, 29 August 2025 2:42 PM
To: s47E(c), s47F
Subject: FW: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion [SEC=OFFICIAL]

FI

Kind regards,

s47E(c), s47F

From: s47F
Sent: Friday, 29 August 2025 2:39 PM
To: s47E(c), s47F
Subject: RE: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion [SEC=OFFICIAL]

Hi s47E(c), s47F

Just letting you know that I have forwarded the invite to s47F, who will also be joining the call, so there will be a total of four MSD representatives at the meeting.

Thank you, and have a great weekend.

s47F

msd-australia.com.au

MSD

I acknowledge the Traditional Owners and Custodians of the lands on which I live, work and travel, whose cultures and customs have nurtured, and continue to nurture this land since the Dreamtime. I pay my respects to Elders past, present and emerging.

From: s47F
Sent: Wednesday, 27 August 2025 4:33 PM
To: s47E(c), s47F @health.gov.au>
Cc: s47F >; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion [SEC=OFFICIAL]

Hi s47E(c), s47F

Happy with that approach. Looking forward to our discussion next week.

Kind regards,
s47F

s47F

s47F

msd-australia.com.au

MSD

I acknowledge the Traditional Owners and Custodians of the lands on which I live, work and travel, whose cultures and customs have nurtured, and continue to nurture this land since the Dreamtime. I pay my respects to Elders past, present and emerging.

From: s47E(c), s47F @health.gov.au>
Sent: Wednesday, 27 August 2025 2:54 PM
To: s47F
Cc: s47F >; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion [SEC=OFFICIAL]

EXTERNAL EMAIL– Use caution with any links or file attachments.
Hi s47F

I agree we will likely need a follow up meeting, let's discuss timing of that meeting once we chat next week and we have an idea of what questions remain outstanding and your team has developed its thoughts on the minutes and post-PBAC meeting discussion.

Kind regards,

s47E(c), s47F

From: s47F
Sent: Wednesday, 27 August 2025 11:52 AM
To: s47E(c), s47F @health.gov.au>
Cc: s47F >; s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Subject: RE: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion

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Hi s47E(c), s47F

We can do 3pm on Wednesday 3 September (thank you for sending the invite just now).

Would it be possible to arrange a second meeting once s47E(c), s47F is back? s47G(1)(b)

Kind regards,
s47F

s47F

msd-australia.com.au

MSD

I acknowledge the Traditional Owners and Custodians of the lands on which I live, work and travel, whose cultures and customs have nurtured, and continue to nurture this land since the Dreamtime. I pay my respects to Elders past, present and emerging.

From: s47E(c), s47F @health.gov.au
Sent: Wednesday, 27 August 2025 11:14 AM
To: s47F
Cc: s47F ; s47E(c), s47F @health.gov.au; s47E(c), s47F @health.gov.au
Subject: [SEC=OFFICIAL] Re: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion

EXTERNAL EMAIL– Use caution with any links or file attachments.
Hi s47F

Thanks for your email. We are happy to facilitate a meeting, s47E(c), s47F is currently away until 16 September but I appreciate that may be too far away given the timelines. I've liaised with his team and we can do 3pm on Wednesday 3 September if that suits you and s47F

There may be some aspects of the below that we will need to get s47E(c), s47F views on when he is back in order to finalise advice but I expect we'll be able to cover enough for you to make a start on the work in the interim. If you would prefer to wait until s47E(c), s47F returns please let me know and I can set a meeting up for the week of 16 September instead but otherwise I'll send invites out for next week shortly.

Kind regards,

s47E(c), s47F

From: s47F
Sent: Tuesday, August 26, 2025 9:35 AM
To: s47E(c), s47F @health.gov.au>; s47E(c), s47F @health.gov.au>
Cc: s47F
Subject: [Sensitive] Pembrolizumab Multi-indication Proposal | Follow-up Discussion

Sensitive

Hi s47E(c), s47F ,

Thanks for meeting with us last week and for your ongoing support of this proposal so that it can be considered at an upcoming PBAC meeting. As we discussed, it would be helpful to schedule a call to clarify the information needed to address the concerns raised in our minutes and the post- PBAC meeting.

We would like to focus on the following points:

s38

Would it be possible to organise a meeting next week on Tuesday 2 Sept at 10-11am, Wednesday 3 September after 2pm, or Thursday 4 September after 1pm? s47F is away on leave so s47F (cc'd) and myself will attend from an MSD perspective.

Kind regards,

s47F

msd-australia.com.au

I acknowledge the Traditional Owners and Custodians of the lands on which I live, work and travel, whose cultures and customs have nurtured, and continue to nurture this land since the Dreamtime. I pay my respects to Elders past, present and emerging.

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s47E(c), s47F

From: s47E(c), s47F
Sent: Friday, 31 October 2025 12:31 PM
To: s47F
Cc: s47E(c), s47F
Subject: MSD pembro revised proposal [SEC=OFFICIAL]
Attachments: MSD_Pembrolizumab_Broad listing_Resubmission_10 Oct 2025_circ.docx

Dear s47F),

Following on from our discussion yesterday in the pre-PBAC meeting, please find attached the revised proposal from MSD for a broad listing of pembro. s22

I understand this may be of use as we discuss pembro next week, noting that we also need to consider the current application on its own merits without pre-empting other decisions around broad listing.

We are proposing bringing this to the December meeting for review, alongside a broader discussion for how to manage additional PD-1s entering the market. s47E(c), s47F will bring together an overview for consideration as usual.
s47E(c), s47F team is working through the models and is much happier with the transparency of the data and will contribute to the overview.

Regards,

s47E(c), s47F

PBAC Secretary | Director, PBAC Governance
Pharmaceutical Assessment Branch
Office of Health Technology Assessment

Technology Assessment and Access Division
Australian Government Department of Health, Disability and Ageing
T: 02 s47E(c), s47F @health.gov.au
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

s47E(c), s47F

From: s47E(c), s47F
Sent: Thursday, 4 December 2025 8:55 PM
To: s47E(c), s47F
Cc: s47E(c), s47F
Subject: FW: [Confidential] RE: Pembrolizumab Broad Listing | UCM and Proposed PBS Restriction [SEC=OFFICIAL]
Attachments: Item 11.12 Pre-PBAC Response for Pembrolizumab - KEYTRUDA - MSD.docx; s22

OFFICIAL

Hi all,

Please see attached MSD's pre-PBAC response for the broad listing overview.

s22

s47E(d)

Kind regards,

s47E(c), s47F

S38