PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2025 PBAC MEETING

Single drug/vaccine agenda items

The PBAC outcomes and recommendations are presented in alphabetical order by agenda item name.

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, CATEGORY/TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	OUTCOME DETAILS
BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms Blincyto® AMGEN AUSTRALIA PTY LTD (Change to existing listing)	Acute lymphoblastic leukaemia (ALL) Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)	To consider an amendment to clarify that newly diagnosed B-ALL Ph+ patients have a subsidised chemotherapy-free option: Induction treatment with a tyrosine kinase inhibitor (TKI) and corticosteroids, and consolidation treatment that includes blinatumomab.	Recommended	The PBAC recommended amendments to the Pharmaceutical Benefits Scheme (PBS) listing for blinatumomab for newly-diagnosed patients with Pre-B-cell ALL: • to include consolidation treatment for Philadelphia chromosome positive (Ph+) patients who have achieved a complete haematological response to induction treatment with a TKI and corticosteroids, without requiring prior combination with chemotherapy; and • to remove the requirement for all patients to be minimal residual disease (MRD) negative in order to be eligible for continuing treatment. The PBAC considered this would benefit patients who could not tolerate chemotherapy or for whom chemotherapy was contraindicated. The PBAC noted the results of the single-arm Phase 2 D-ALBA study which indicated high remission rates with dasatinib and corticosteroid induction followed by blinatumomab, in which: nearly all patients achieving complete haematologic remission; molecular response rates improved substantially after subsequent blinatumomab treatment and continued to increase with additional cycles; and long-term follow-up demonstrated favourable survival outcomes. The PBAC also recommended flow-on changes to the relapsed and refractory Pre-B-cell ALL to ensure that Ph+ patients who received initial treatment (for newly diagnosed Pre-B-cell ALL) with a TKI and corticosteroids and consolidation treatment with blinatumomab are then eligible for blinatumomab (or inotuzumab ozogamicin) in the relapsed or refractory setting. The PBAC noted that the removal of the MRD-based continuation criteria from the listing for newly-diagnosed patients was in line with clinical practice, the TGA Product Information and the D-ALBA study, and that the PBS listing would remain unavailable to patients who had progressive disease. The PBAC considered that the proposed changes were clinically appropriate and that the expanded listing would remain cost-effective given the expected clinical outcomes for patients. The PBAC advised that the expansion to include Ph+ patients previously treated with a TKI (who are intolerant to chemotherapy) was likely captured in previous financial estimates for blinatumomab, but that the removal of the MRD-based continuation criteria

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				would be expected to result in a financial impact, which should be incorporated into the expenditure caps under the existing Risk Sharing Arrangement (RSA), accounting for offsets in the relapsed or refractory setting.
EPLERENONE Tablet 25 mg Tablet 50 mg Inspra® VIATRIS PTY LTD Matters outstanding (Change to existing listing)	Heart failure	To consider an amendment to the clinical criteria for eplerenone to align with clinical guidelines for the management of heart failure. This item was deferred at the July 2025 PBAC meeting.	Recommended	The PBAC recommended amendments to the current PBS restriction for eplerenone (Inspra®) to align with contemporary clinical guidelines for the management of heart failure (HF). In its review of the updated restriction, the PBAC considered minor flow-on changes would also apply to sacubitril + valsartan for HF. The PBAC noted recent literature highlighting eplerenone's improved efficacy and safety profile over spironolactone in the HF population. The PBAC also noted that the amended listing will result in broader access to eplerenone, and provide an alternative to spironolactone, the main mineralocorticoid receptor agonist (MRA) used for HF on the PBS. The PBAC's recommendation was based on eplerenone's cost-effectiveness as compared to spironolactone. The PBAC noted the considerable price reduction of eplerenone since its first listing in 2006 and accepted that it was cost-effective at the current price.
HYDROXYCHLOROQUINE Tablet containing hydroxychloroquine sulfate 200mg (LI) APO- HYDROXYCHLOROQUINE HEQUINEL HYDROXYCHLORQUINE GH PLAQUENIL® Apotex Pty Ltd Arrow Pharma Pty Ltd Generic Health Pty Ltd Sanofi-Aventis Australia Pty ltd (Change to existing listing)	Unrestricted	To consider an increase to the number of repeats from one to three.	Recommended	The PBAC recommended amending the PBS listing for hydroxychloroquine sulfate 200 mg tablets to increase the maximum number of repeats per prescription from one repeat to three repeats. The PBAC noted correspondence received from a clinical organisation which sought the increase in maximum repeats on the basis it would support patient access and continuity of treatment by aligning the duration of supply with the standard review cycle for rheumatology follow up visits. The PBAC noted the change to the PBS listing is not expected to alter the prescribed dose of hydroxychloroquine, the overall treatment duration, or the eligible population. As such, it did not expect the change to add costs to the PBS.

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NUSINERSEN 12mg/5mL intrathecal injection Spinraza® BIOGEN AUSTRALIA PTY LTD (Change to existing listing)	Spinal muscular atrophy (SMA)	To clarify nusinersen and risdiplam restrictions following gene therapy.	Recommended	The PBAC recommended amending the initial treatment phase listings of nusinersen to allow treatment in children with spinal muscular atrophy (SMA) who have received gene therapy with onasemnogene abeparvovec outside the PBS. This was to address the unintended exclusion of a small subset of children from receiving PBS treatment. This exclusion resulted from the PBAC's September 2021 recommendation to amend the nusinersen and risdiplam listings to require that children be untreated with gene therapy, or have prior PBS approval for gene therapy, to access these medicines for the treatment of SMA. The PBAC recommended that the same amendments be made to the risdiplam listings and the listings that allow these children to switch between nusinersen and risdiplam treatment if required. This approach aligned with the PBAC's intent to provide equitable access and the best possible clinical outcomes for all eligible children, regardless of their prior treatment pathway.

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PEMBROLIZUMAB Solution concentrate for I.V. infusion 100 mg in 4 mL Keytruda MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (Change to existing listing)	Advanced and metastatic cancers	To consider a revised proposal for a broad (multi-cancer) listing for pembrolizumab for advanced and metastatic cancers.	Recommended	The PBAC recommended a broad (multi-cancer) listing of pembrolizumab for the treatment of advanced or metastatic cancers. The PBAC welcomed the sponsor's revised approach to the restriction criteria and noted this had largely addressed its concerns from the July 2025 submission, particularly regarding access for patients with rare cancers. The PBAC recalled it had recommended nivolumab ± ipilimumab for a broad listing for advanced and metastatic cancers in September 2025. The PBAC considered it would be appropriate for pembrolizumab to join the Risk Sharing Arrangement (RSA) recommended for the nivolumab ± ipilimumab broad listing, should that recommendation proceed to listing, and that the restriction wording for both broad listings be made consistent. The PBAC considered there would be several indications, including a number that are already PBS-listed, where both pembrolizumab and nivolumab (± ipilimumab) would be treatment options in the same or similar population. Therefore, a shared RSA across the immunotherapies would more effectively manage the intended price discounts and total budget impact of the broad listings. The PBAC reaffirmed its September 2025 advice that the successful implementation and appropriate use of such broad listings (nivolumab ± ipilimumab and pembrolizumab) would be crucial to support the future consideration of this and any similar broad listing proposals. The PBAC reiterated the importance of engagement from sponsors, patient groups, clinical peak bodies and healthcare practitioners in supporting the ongoing viability of the listing and added the necessity for both sponsors to be aligned in their approach. The PBAC requested the Department review how this listing will be used after three years of listing to ensure the use remained consistent with its intention. The PBAC noted that broad listing requests for additional PD-L(1) inhibitors may be sought in the future. It considered this would be reasonable but that each sponsor would need to lodge a submission demonstrating efficacy, safety and cost-effectiveness in a broad setting.

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RAXTOZINAMERAN I.M. injection, suspension for injection containing raxtozinameran 30 micrograms Comirnaty® Omicron XBB.1.5 PFIZER AUSTRALIA PTY LTD Matters outstanding (New NIP listing)	Prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2	To request a National Immunisation Program listing for the prevention of COVID-19 caused by the SARS-CoV-2 virus in adults aged ≥ 18 years at increased risk of severe COVID-19 disease.	Recommended	The PBAC recommended that the COVID-19 vaccine, Comirnaty®, be listed on the National Immunisation Program (NIP). This vaccine was recommended for use in in four populations of adults as requested by the sponsor: • adults aged 75 years or more (2 doses per year) • adults aged 65–74 years (1 dose per year) • adults aged 18–64 years with severe immunocompromise (1 dose per year) • Aboriginal and Torres Strait Islander adults aged 50–74 years (1 dose per year). The PBAC noted the requested populations and doses were based on updated advice from the Australian Technical Advisory Group on Immunisation (ATAGI). This is a smaller group than current arrangements under the National COVID-19 Vaccination Program (NCVP). This December 2025 consideration followed the PBAC's May 2025 consideration of raxtozinameran (Comirnaty Omicron XBB.1.5). The PBAC noted new vaccine versions are developed as the virus changes, and that the most recent Comirnaty vaccine at the time was the LP.8.1 version (registered by the TGA in October 2025). Consistent with its advice in May 2025, the PBAC considered it was important to use vaccines that target current variants of the COVID-19 virus. The PBAC supported a platform recommendation for Comirnaty. This means the PBAC's recommendation can also apply to future updated versions of Comirnaty made using the same vaccine platform, known as the BNT162b2 platform, which will support timely access to updated vaccines through the NIP after TGA approval. This PBAC recommendation is the first for a COVID-19 vaccine and is a necessary step to enable transition of COVID-19 vaccines from the NCVP to the NIP. The PBAC considered ongoing protection from COVID-19 remains important, noting COVID-19 was the leading cause of acute respiratory infection mortality in Australia between 2022 and 2024 (Australian CDC, *Australian Respiratory Surveillance Report* 30 Dec 2024–26 Jan 2025). The PBAC considered the sponsor's economic assumptions were not appropriate and advised the analysis should use more conservative assumptions. Using the PBAC's recommended assumptions at the sponsor's proposed price, the PBAC considered the incremental cost-effectiveness ratio (ICER) was unacceptably high. On this basis, the PBAC recommended that a lower price would be required to ensure the vaccine is cost-effective in the proposed circumstances of use.

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				The PBAC noted and accepted that with the revised assumptions and a price reduction, there would still be a very high cost to government of the proposed NIP listing.
RESPIRATORY SYNCYTIAL VIRUS VACCINE Powder and suspension for injection (0.5 mL) Arexvy® GLAXOSMITHKLINE AUSTRALIA PTY LTD Matters outstanding (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request National Immunisation Program (NIP) listing for the prevention of lower respiratory tract disease (LRTD) caused by RSV for adults 75 years of age and above, and for Aboriginal and Torres Strait Islander peoples aged 60 to 74 years.	Recommended	The PBAC recommended that recombinant respiratory syncytial virus (RSV) pre-fusion F protein (RSVPreF3 OA) vaccine (Arexvy®) be listed on the National Immunisation Program (NIP) for the prevention of lower respiratory tract disease (LRTD) caused by RSV in adults 75 years of age and above, and in Aboriginal and Torres Strait Islander peoples aged 60 to 74 years. Consistent with previous advice, the PBAC considered there is a high clinical need for vaccines, such as Arexvy, to reduce the risk of RSV in older adults. The PBAC recalled that it had previously recommended Arexvy in July 2025, and at that time it had advised the parameters to ensure that the vaccine was cost-effective in the proposed circumstances of use. The PBAC noted that the sponsor had provided a proposal for consideration including a revised price and updated cost inputs to reflect current cost data. The PBAC did not consider any new clinical data as part of this consideration, therefore the clinical conclusions were unchanged from its advice in July 2025. The PBAC considered that the revised inputs in the cost-effectiveness analysis were acceptable, and that the vaccine was cost-effective at the price proposed. The PBAC reaffirmed the equi-effective doses for comparing Arexvy with the RSVpreF vaccine (Abrysvo®): one dose (120 micrograms) of Arexvy is equivalent to one dose (120 micrograms) of Abrysvo.

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SELADELPAR Capsule 10 mg Livdelzi® GILEAD SCIENCES PTY LTD Matters outstanding (New PBS listing)	Primary biliary cholangitis (PBC)	To request a General Schedule Authority Required (STREAMLINED) listing for the treatment of PBC in patients who have had an inadequate response to first line therapy with ursodeoxycholic acid (UDCA) or are intolerant to UDCA.	Recommended	The PBAC recommended the PBS listing of seladelpar for the treatment of primary biliary cholangitis (PBC), noting that the TGA supported registration of seladelpar in Australia. The PBAC noted previous input from the Liver Foundation on the significant impact of PBC on quality of life. The PBAC noted it had previously considered seladelpar was as effective as obeticholic acid (OCA) at reducing markers of liver damage and improving cholestasis, with similar safety. The PBAC also noted patients treated with seladelpar reported improved itching symptoms and lower rates of PBC-related pruritus than patients treated with OCA, and acknowledged pruritus is a significant issue for people with PBC. The PBAC considered a price premium for seladelpar over OCA would be reasonable (consistent with its approach for elafibranor in March 2025), given the potential reduction in PBC-related pruritus compared to OCA. The PBAC considered 10 mg of seladelpar once daily was equivalent to 5 mg or 10 mg of OCA once daily. The PBAC considered seladelpar should join the risk sharing arrangement (RSA) for OCA with no increase in the expenditure caps. The PBAC noted that listing seladelpar would require flow-on changes to the existing OCA and elafibranor PBS restrictions to enable patient switching between seladelpar, OCA and elafibranor. Flow-on changes to the elafibranor listing would also be required to allow prescribing for immunocompromised patients and to remove the hepatic decompensation caution.

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VELMANASE ALFA Powder for I.V. infusion 10 mg Lamzede® CHIESI AUSTRALIA PTY LTD Matters outstanding (New PBS listing)	Alpha-mannosidosis (AM)	To request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing as an enzyme replacement therapy for the treatment of non-neurological manifestations in patients with AM.	Recommended*	The PBAC recommended listing velmanase alfa (Lamzede®) on the PBS for the treatment the non-neurological symptoms of alpha-mannosidosis (AM). The PBAC acknowledged that AM is an extremely rare and devastating genetic condition. It is caused by problems with the alpha-mannosidase enzyme, which leads to a build-up of oligosaccharides (complex sugar molecules) throughout the body and affects multiple body systems. The PBAC noted there are currently no effective pharmacological treatments available in Australia for this condition. The PBAC noted that the sponsor's response to the deferral addressed the previous concerns regarding the proposed restriction and provided additional clinical and patient-relevant data regarding the benefits of treatment. The PBAC considered the additional information supported longer-term meaningful clinical benefits for people with AM. The PBAC recommended listing on the basis that a further price reduction be provided, noting that it considered the price proposed in the submission was not cost-effective, but that cost-effectiveness could be achieved at a lower price.

* Pricing Pathway A

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Other agenda items

AGENDA ITEM, FORM(S), STRENGTH(S), SPONSOR	DRUG TYPE AND USE	PURPOSE OF AGENDA ITEM	PBAC OUTCOME
Designated Registered Nurse Prescribing	Not Applicable	To provide advice on developed principles that will be used to assess the suitability of each PBS medicine for designated registered nurse PBS prescribing.	The PBAC considered how the PBS could safely support prescribing by designated registered nurse (RN) prescribers in the future. Designated RN prescribers are registered nurses endorsed under the Nursing and Midwifery Board of Australia Registration standard. Designated RN prescribers would be able to prescribe certain medicines in partnership with an authorised health practitioner, supported by a prescribing agreement and clinical governance arrangements. The PBAC endorsed guidance principles to help assess which PBS medicine listings may be suitable for designated RN prescribing. The principles use a tiered approach: an initial screen to identify medicines that may raise significant concerns, followed by further considerations (such as potential impacts on patient access and other practical issues) where the initial screen identifies minimal concerns. The PBAC also endorsed a revised timeline for a staged PBAC review of PBS listings for designated RN prescribing. The PBAC noted that implementation will also depend on legislative and jurisdictional settings. A Bill introduced to Parliament on 26 November 2025 proposes recognising designated RN prescribers as PBS prescribers from mid-2026, and state and territory medicines and poisons laws may also need to be updated.
Biologics for Ulcerative Colitis and Crohn Disease in Paediatric-to-adult Transition Multiple drugs, brands and sponsors	Crohn disease Ulcerative colitis	To provide advice regarding PBS subsidised access to biological and targeted synthetic disease modifying drugs (b/tsDMARD) for adolescent/adult patients with moderate to severe ulcerative colitis (UC) or severe Crohn disease (CD) where treatment was initiated during childhood and accessed via non-PBS pathways.	The PBAC recommended changes to the PBS listing of golimumab, ozanimod, tofacitinib, upadacitinib, ustekinumab, vedolizumab to support access for people with ulcerative colitis (UC) and Crohn disease (CD) who started advanced therapy during childhood. Some young people start these medicines through non-PBS pathways (for example, hospital individual patient use programs or compassionate access schemes). By the time they turn 18, treatment may have controlled symptoms and lowered biomarkers, which can make it hard to meet the disease-severity entry criteria in the adult PBS listings. To avoid treatment disruption and potential clinical relapse, the PBAC recommended a pathway for these patients to move onto the adult PBS listings. Under the amended listings, prescribers will need to show that: • treatment started before age 18 through a non-PBS pathway; • the patient met the paediatric PBS criteria for initial therapy at the time treatment started; and • the patient has demonstrated or maintained an adequate clinical response. The PBAC also supported changes to PBS restrictions for subcutaneous infliximab so they align with the paediatric eligibility criteria already used for intravenous infliximab. This reflects evolving clinical practice, where subcutaneous infliximab is increasingly used in paediatric inflammatory bowel disease to reduce hospital infusion burden and

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			improve convenience. The PBAC noted clinicians cited real-world evidence that subcutaneous infliximab is effective and well tolerated in this population. The PBAC noted these changes are intended for a small, clinically stable group transitioning from paediatric to adult care, and are not expected to expand the overall PBS-eligible population. The PBAC reviewed financial estimates and considered the amendments are not expected to add costs to the PBS.
PBS medicines for Pulmonary Arterial Hypertension Multiple drugs, brands and sponsors	Pulmonary Arterial Hypertension	To consider the impact on drug utilisation and financial implications of allowing earlier access to dual therapy in patients with World Health Organisation (WHO) functional class II PAH disease.	The PBAC recommended that the availability of certain PBS listed medicines for the treatment of pulmonary arterial hypertension (PAH), that is, endothelin receptor antagonists (ERAs) and phosphodiesterase-5 inhibitors (PDE-5i), be broadened to allow combination use earlier in the disease course, to align PBS restrictions more closely with international treatment guidelines. The PBAC noted that flow-on PBS restriction changes would be required for epoprostenol and iloprost. The PBAC advised that the additional cost to Government of this amendment was reasonable and likely overestimated. The PBAC asked the Department to perform further work for consideration at a future meeting to further review PBS restrictions for consistency with treatment guidelines and practices, including broadening access to another PBS-listed PAH medicine (riociguat). The PBAC advised it would invite an application from the riociguat sponsor requesting riociguat to be used with an endothelin receptor antagonist (ERA), and to estimate the likely change in use and the financial impact of this broader listing.
Review of PBS Prescriber Bag: Tranche 2 Multiple drugs, brands and sponsors	Multiple indication Multiple drugs	To consider stakeholder requests for inclusion of additional items in the Prescriber Bag and recommend which items should be added to the Prescriber Bag.	The PBAC provided advice on the suitability of a second and final tranche of medicines proposed as new additions to the PBS Prescriber Bag schedule by stakeholders. The PBAC reviewed the suitability of all requested medicines for Prescriber Bag listing and considered that most proposed requests for new additions did not satisfy the intent for inclusion in the PBS Prescriber Bag. The PBAC requested that the Department provide further information on specific medicines for its consideration at the March 2026 PBAC meeting. The PBAC recommended retaining furosemide tablets (pack size 50) on the Prescriber Bag. The PBAC agreed for the Department to continue working on the establishment of a palliative care listing of midazolam, rather than prescribers relying on Prescriber Bag supplies for this purpose. The PBAC acknowledged stakeholder views that highlight the Prescriber Bag does not address broader access issues to medicines in circumstances such as rural and remote geographical location and access to medicines for certain vulnerable populations or specific population groups. However, the PBAC agreed that development of an appropriate policy response to address broader access to medicines issues is a matter for Government and beyond the scope of the Review of the contents of the Prescriber Bag schedule. The PBAC supports such exploration. The PBAC requested that the Department provide further information (e.g. proposed price, financial implications) to inform further consideration of a small number of medicines (the morning after pill, MS 2-step, prednisolone oral

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			liquid and a corticosteroid tablet) given they do not meet intent the of the Prescriber Bag, however there is strong stakeholder support and PBAC interest in ensuring timely access to these medicines.

Version 2:
Amendment:

1. BLINATUMOMAB Powder for I.V. infusion 38.5 micrograms (Blincyto®) – Added PBAC outcome and outcomes details.

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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.

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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.