PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
SEPTEMBER 2026 PBAC MEETING

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

Single drug/vaccine agenda items

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
BUDESONIDE WITH GLYCOPYRRONIUM AND FORMOTEROL Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 14.4 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses Breztri Aerosphere® ASTRAZENECA PTY LTD Category 2 (New PBS listing)	Severe asthma	To consider a request for listing of a new form of budesonide with glycopyrronium and formoterol for the maintenance treatment of severe asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta agonist (LABA) and an inhaled corticosteroid (ICS) who experienced at least one severe asthma exacerbation in the 12 months prior to having first commenced treatment for severe asthma.	Recommended	The PBAC recommended listing of the fixed dose combination (FDC) of budesonide (BUD) with formoterol (FOR) and glycopyrronium (GLY) (BUD/FOR/GLY) for maintenance treatment of severe asthma. The PBAC welcomed the input from Asthma Australia supporting the listing of BUD/FOR/GLY for this use. The input highlighted the burden severe asthma can place on people and their families and noted that BUD/FOR/GLY offered another inhaler option. Based on the evidence included in the submission, the PBAC was satisfied that medium dose BUD/FOR/GLY was as effective as medium dose beclometasone (BEC)/FOR/GLY and had similar safety. The PBAC considered that the cost of BUD/FOR/GLY should be no greater than the lowest price combination at approved ex-manufacturer price level of the PBS listed components of triple therapy that are available for asthma at comparable doses. The PBAC advised the equi-effective doses for severe asthma were: BUD/FOR/GLY (160/5/14.4 µg), 2 actuations twice daily equals BEC/FOR/GLY (100/6/10 µg), 2 actuations twice daily. The PBAC advised that the equi-effective doses of alternative therapies for severe asthma should be based on that previously accepted by the PBAC at the time of recommendation. The PBAC agreed with the evaluation that mometasone should be included in the administrative advice describing ICS. The PBAC also considered that the administrative advice on therapies that should not be used in combination with BUD/FOR/GLY should refer to ICS/LABA/LAMA therapy. It was considered appropriate for both of these changes to flow on to other listings that have the relevant Concept IDs.

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CEMIPLIMAB BROAD (MULTI-CANCER) LISTING Solution concentrate for I.V. infusion 350 mg in 7 mL Libtayo® MEDISON PHARMA AUSTRALIA PTY LIMITED Other business (Other matters)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of cemiplimab for immunotherapy-sensitive advanced or metastatic cancers.	Advice Provided	The PBAC considered that the preliminary information provided was sufficient to support a formal submission for a broad (multi-cancer) PBS listing of cemiplimab for advanced or metastatic cancers. The PBAC considered the clinical evidence presented indicated cemiplimab may offer benefits over existing PBS-reimbursed broad listings in basal cell carcinomas and niche rare cancers. The PBAC anticipated that, should the sponsor proceed to a formal submission for broad listing of cemiplimab, there would be likely no increase in utilisation and no net cost increase to government expenditure, as use of cemiplimab would be expected to replace that of nivolumab, ipilimumab and pembrolizumab broad listings and would use the same cost structure. The PBAC welcomed the consumer engagement undertaken as part of this proposal.

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CLOZAPINE Oral liquid 50 mg per mL, 100 mL, Tablet 200 mg, Tablet 100 mg, Tablet 50 mg, Tablet 25 mg Multiple Douglas Pharmaceuticals Australia Pty Limited, Juno Pharmaceuticals Pty Ltd, Viatris Pty Ltd Internal submission (Change to existing listing)	Schizophrenia	To consider proposed changes to the clozapine listings that would shorten the initial treatment period under the Section 100 Highly Specialised Drugs Program, while retaining initial treatment under that program and continuing treatment under the Section 100 Community Access Program.	Recommended	The PBAC recommended the period of supply required under the initial therapy Section 100 Highly Specialised Drugs (s100 HSD) Program Public/Private Hospital listing for clozapine to be reduced from 18 weeks to at least 4 weeks. The change was to facilitate patients being able to obtain supply from a registered community pharmacy within the first 18 weeks of therapy, rather having to attend a hospital pharmacy. The PBAC noted that the change was not intended to supersede the current safety monitoring requirements for clozapine. The PBAC welcomed and acknowledged input from Advanced Pharmacy Australia (AdPha) and the Royal Australian and New Zealand College of Psychiatrists (RANZCP) describing the challenges that consumers may have in collecting supply of clozapine from hospital pharmacies, particularly for those living in non-metropolitan areas, or managing a severe or chronic mental health condition. The PBAC noted that AdPha's proposal was intended to allow clinically stabilised consumers to access medication closer to home following discharge from hospital care. The PBAC also noted input from RANZCP supporting the proposal from AdPha; however, an initial period of supply from a hospital pharmacy and prescribing required to be linked to a hospital setting should be retained. Additionally, the PBAC noted concerns from sponsors around patient safety and monitoring. The PBAC advised that the change in listing would not change the safety monitoring requirements for clozapine as imposed by the Therapeutic Goods Administration. The PBAC noted the change would not preclude psychiatrists or authorised medical practitioners prescribing the first 18 weeks of therapy for access through a hospital pharmacy only, if they considered it appropriate. The PBAC considered it appropriate to reduce the maximum quantity to 100 (from 200) to allow for variable dosing arrangements for all strengths of the oral tablets, up to a maximum of 4 weeks. The PBAC advised that it would be appropriate to include a prescribing instruction that reinforces the responsibilities of prescribers and dispensing pharmacists for complying with monitoring requirements. These include more frequent monitoring in the first 18 weeks of treatment. The PBAC also noted that any changes to the restriction wording would be flowed onto the clozapine orally disintegrating forms of clozapine of the associated strength, following their recommendation at the July 2026 PBAC meeting.

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DURVALUMAB BROAD (MULTI-CANCER) LISTING Solution concentrate for I.V. infusion 500 mg in 10 mL Imfinzi® AstraZeneca Pty Ltd Other business (Other matters)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of durvalumab for immunotherapy-sensitive advanced or metastatic cancers.	Advice Provided	The PBAC considered that the preliminary information presented was not sufficient to support a positive recommendation for a broad (multi-cancer) listing for durvalumab for advanced or metastatic cancers. The PBAC considered that the sponsor would need to agree to the financial and economic expectations in the Principles as part of any revised proposal. The PBAC noted that inclusion of clinician and consumer input, alongside additional clinical evidence that may become available demonstrating additional benefit and/or superiority over currently broad listed alternatives if the portfolio of evidence changes, would provide additional support for the clinical need and justification for a broad listing of durvalumab.
GOSERELIN Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe Zoladex® AstraZeneca Pty Ltd Category 2 (Change to existing listing)	HR+ Breast Cancer	To consider a request for the listing of goserelin subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe for the treatment of hormone receptor positive (HR+) breast cancer.	Recommended	The PBAC recommended that the General Benefit listing for goserelin 10.8 mg subcutaneous implant be made unrestricted. The PBAC noted that the submission requested a breast cancer indication be added to the existing PBS listing for goserelin 10.8 mg implant. However, the sponsor had made a further request for an unrestricted listing. The PBAC considered that, among matters, an unrestricted listing for goserelin 10.8 mg would be acceptable at the current AEMP. The PBAC noted and welcomed input from individuals, health professionals, and professional organisations. The PBAC acknowledged the importance of having a range of GnRH medicines available on the PBS and supporting patient preferences. The PBAC advised that an unrestricted listing would align with contemporary and evidence-based clinical practice.

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NIRSEVIMAB Solution for injection 50 mg in 0.5 mL pre-filled syringe Solution for injection 100 mg in 1 mL pre-filled syringe Beyfortus™ SANOFI-AVENTIS AUSTRALIA PTY LTD Matters outstanding (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To request a National Immunisation Program listing for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season; and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season	Recommended	The PBAC recommended that nirsevimab be available through the National Immunisation Program (NIP) for the prevention of lower respiratory tract illness (LTRI) caused by respiratory syncytial virus (RSV) in neonates and infants born during or entering their first RSV season, and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The PBAC noted the ATAGI's revised recommendation that nirsevimab should be available for Aboriginal and Torres Strait Islander infants up to 24 months of age in their first and second RSV seasons, irrespective of maternal vaccination status or medical risk factors due to the high burden of disease due to RSV. The PBAC considered this advice should be incorporated in the recommended NIP listing for nirsevimab, alongside the populations for nirsevimab currently described in the Australian Immunisation Handbook (AIH). The PBAC recalled it deferred consideration of nirsevimab at its May 2025 meeting requesting 1) a proposal from the sponsor regarding the price of nirsevimab, and the estimated use and associated financial implications; and 2) confirmation from the Department that a pathway had been established for the listing of passive immunisation strategies on the NIP, thereby allowing monoclonal antibodies such as nirsevimab to be made available on the NIP. The PBAC considered that the sponsor's proposal addressed the outstanding issues related to the cost-effectiveness of nirsevimab when used as an alternative to RSVpreF, and the financial estimates. The PBAC noted in some infants, the use of nirsevimab would provide additional protection that could not be addressed by RSVpreF maternal vaccine, for example for infants whose mother received the RSVpreF vaccine but were born within two weeks from vaccination, which would result in impaired protection from the vaccine. The PBAC also acknowledged that nirsevimab would have additional value for infants at risk of severe disease from RSV, including in their first RSV season despite use of maternal RSVpreF vaccination, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The PBAC considered that the cost-effectiveness of nirsevimab was not adequately addressed in these populations, and that a price reduction would be required to achieve a cost-effective listing. The PBAC noted advice received from the Department, that the legislative framework underpinning the NIP was amended in April 2026 to broaden the definition of a vaccine to allow inclusion of passive immunisation strategies such as nirsevimab.

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NITISINONE Capsule 2 mg, Capsule 5 mg, Capsule 10 mg, Capsule 20 mg, and Oral suspension 4 mg per mL, 90 mL Orfadin® A. Menarini Pty Ltd Internal submission (Change to existing listing)	Hereditary tyrosinaemia type 1 (HT-1)	To consider whether authorised nurse practitioners should be included as eligible prescribers of nitisinone for the treatment of hereditary tyrosinaemia type 1 (HT-1).	Recommended	The PBAC advised that nurse practitioners and non-specialist medical practitioners be added as authorised prescribers of nitisinone as continuing therapy only, for the treatment of hereditary tyrosinaemia type 1 (HT-1). The PBAC further advised that prescribing of nitisinone should be restricted to nurse practitioners and non-specialist medical practitioners with expertise in the management of HT-1 and that patient care must be shared with a physician with expertise in the management of HT-1. The PBAC considered that this approach was consistent with its past advice supporting nurse practitioner prescribing of other HSD medicines. The PBAC noted and welcomed feedback from health practitioners and professional organisations. The PBAC recognised the critical role specialised NPs play within multidisciplinary metabolic centres. It noted nurse practitioners' extensive knowledge and experience, and their significant role in providing timely access to treatment, ongoing monitoring, and continuity of care within the clinic. The PBAC noted the potential benefits of nurse practitioner continuing treatment prescribing, including supporting prescriber capacity for monitoring, clinic schedules, system logistics and patient care. On the basis that HT-1 is a rare disorder managed in specialised centres, the PBAC considered that the addition of nurse practitioners and non-specialist medical practitioners as eligible prescribers would not be expected to change the utilisation of nitisinone or its financial impact on the PBS.

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RESPIRATORY SYNCYTIAL VIRUS VACCINE Solution for injection 50 µg in 0.5 mL pre filled syringe mRESVIA® MODERNA AUSTRALIA PTY LTD Matters outstanding (New NIP listing)	Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)	To consider a request for National Immunisation Program listing for the prevention of lower respiratory tract disease caused by RSV in individuals aged 75 years and older, and Aboriginal and Torres Strait Islander people aged 60 years and older.	Not Recommended	The PBAC did not recommend respiratory syncytial virus vaccine (mRNA-1345; mRESVIA) be a designated vaccine for the purposes of the *National Health Act 1953* for the prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV) in people aged 75 years and older and Aboriginal and Torres Strait Islander peoples aged 60 to under 75 years. The PBAC recalled that in November 2025 it had deferred making a recommendation as it considered the clinical place for mRNA-1345 was uncertain. The PBAC noted that an alternative RSV vaccine (RSVPreF3 OA, Arexvy) was listed on the NIP in May 2026 for the populations proposed for mRNA-1345. The evidence presented did not satisfy the PBAC that mRNA-1345 would be as effective as protein RSV vaccines (RSVpreF and RSVPreF3 OA).The PBAC therefore concluded there was no clinical place for mRNA-1345 on the NIP vaccination schedule. The PBAC noted this advice was consistent with advice received from the ATAGI. Sponsor's Comment: *Moderna is disappointed with the decision and maintains that mRESVIA is an effective vaccine for older adults against the impacts of LRTD and severe disease following RSV infection.* *Moderna notes that the evidence presented did not satisfy the PBAC that mRNA-1345 would be as effective as other protein RSV vaccines.* *Moderna will continue working with ATAGI and the PBAC as more evidence becomes available from the use of RSV vaccines in real-world settings.*

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TARLATAMAB Powder for injection 1mg, powder for injection 10 mg Imdelltra® AMGEN AUSTRALIA PTY LIMITED Early resolution (New PBS listing)	Extensive-stage small cell lung cancer	To reconsider a request for listing tarlatamab for the second-line and subsequent treatment of adult patients with extensive-stage small cell lung cancer whose disease has progressed on or after platinum-based chemotherapy.	Recommended	The PBAC recommended tarlatamab for the treatment of extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after first line treatment with platinum-based chemotherapy. The PBAC recalled the input it received from healthcare professionals and individuals prior to its March 2026 meeting, and welcomed additional input provided for this resubmission from a health care professional and an individual. The PBAC noted that there was currently a high clinical need for effective therapies for ES-SCLC, noting that patients currently have few effective treatment options, with only modest clinical benefit, and typically face rapidly progressive disease, substantial symptom burden, and short survival. While the resubmission (using the early resolution pathway) addressed the outstanding issues related to the restriction criteria and financial estimates, the PBAC noted it did not implement the requested changes to the economic model requested in March 2026. The PBAC considered that a substantial price reduction was required to achieve a cost-effective listing and a risk sharing arrangement was required to mitigate the risk that people would access the subsidy outside the proposed criteria.
TISLELIZUMAB BROAD (MULTI-CANCER) LISTING Solution concentrate for I.V. infusion 100 mg in 10 mL Tevimbra® BEONE MEDICINES AUS PTY LTD Other business (Other matters)	Broad listing for immunotherapy-sensitive advanced or metastatic cancers	To consider and provide preliminary advice on a sponsor-provided summary of clinical evidence, intended to support a future submission requesting a broad PBS listing of tislelizumab for immunotherapy-sensitive advanced or metastatic cancers.	Advice Provided	At this stage, the PBAC considered that the preliminary information presented was not sufficient to support a formal submission for a broad (multi-cancer) listing for tislelizumab for advanced or metastatic cancers. The PBAC considered a revised proposal for a broad listing for tislelizumab may be appropriate if additional clinical evidence demonstrating a benefit and/or superiority over currently broad listed alternatives becomes available or the portfolio of evidence changes. The PBAC noted the inclusion of clinician and consumer input alongside the clinical evidence would provide additional support for the clinical need and justification for a broad listing of tislelizumab.

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Various drugs, strengths, brands, and sponsors

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 advise on which medicines within tranche 3 (body systems - Hormonal and systemic, Antiinfectives, Respiratory, Sensory, Musculo Skeletal, Various, and Antineoplastic) are suitable for prescribing by designated RN prescribers.	The PBAC recommended adding designated RN prescribers as authorised PBS prescribers for selected medicines in the ATC Body systems H, J, L, M, R, S and V from which nurse practitioners are existing eligible prescribers, with some medicines restricted to continuing therapy only. The PBAC considered certain medicines are unsuitable to be authorised as a PBS subsidy by designated RN prescribers for at least one of the following reasons in most instances: (i) the diagnosis of the medical condition is complex, (ii) the management of the medical condition, other than diagnosis, is complex, (iii) the medicine is high risk in terms of severe side effects.
REVIEW OF ATTENTION DEFICIT HYPERACTIVITY DISORDER MEDICINES - TRANCHE 1 (GUANFACINE AND ATOMOXETINE) Various drugs, strengths, brands, and sponsors Post-market review (PBS review)	Attention Deficit Hyperactivity Disorder	To: 1. Advise on the proposed amendments to the PBS listings atomoxetine and guanfacine to: • permit subsidised use in patients who have tolerated, but not adequately responded to, stimulant therapy; and • broaden prescriber eligibility beyond specialist-only initiation requirements. 2. Consider the estimated utilisation and financial impact associated with the proposed restriction changes. 3. Note pre-subcommittee and pre-PBAC responses and advice from the Drug Utilisation Sub-Committee (DUSC).	The PBAC recommended changes to PBS restrictions for atomoxetine and guanfacine for the treatment of attention deficit hyperactivity disorder (ADHD), to align eligibility, broaden access where stimulant therapy has been ineffective or clinically inappropriate, and expand authorised prescribers beyond specialist-only for treatment initiation. This work partially addresses recommendations from 2023 Senate Community Affairs References Committee inquiry into ADHD, with a further tranche to follow on the PBS-listing stimulants for ADHD. The recommendation was informed by advice from the Drug Utilisation Sub-Committee (DUSC), stakeholder feedback, and issues raised through the Senate Community Affairs References Committee inquiry. The changes are intended to better align PBS access with contemporary Australian clinical guidelines while maintaining atomoxetine and guanfacine as second-line treatment options. The PBAC supported the revised epidemiological modelling approach and noted the assumptions tested through sensitivity analyses. The PBAC noted that the estimated utilisation and expenditure was substantially higher than previously forecast through a private-market-share approach and acknowledged the uncertainty regarding the size of the untreated population. The PBAC noted that while cost-effectiveness had not been formally established, the proposed changes were likely to represent acceptable value for money in the expanded population. The PBAC supported ongoing monitoring of utilisation and prescribing patterns following implementation.
CITALOPRAM, CLOMIPRAMINE, DESVENLAFAXINE, DULOXETINE, ESCITALOPRAM, FLUOXETINE, FLUVOXAMINE, MIANSERIN, MIRTAZAPINE, MOCLOBEMIDE, NORTRIPTYLINE, PAROXETINE, SERTRALINE and VENLAFAXINE	Antidepressants used for mood, anxiety, obsessive-compulsive, pain-related and other conditions	To consider proposed changes to the PBS restrictions for select low-cost antidepressants, including the estimated financial impact to the PBS, to support broader PBS-subsidised access consistent with contemporary Australian clinical practice.	The PBAC recommended changes to the PBS restrictions for fourteen PBS-listed antidepressants. For 30-day solid oral dosage-form listings, the PBAC recommended amending the current Restricted Benefit listings to Unrestricted Benefit listings, with the indication and eligibility criteria removed. For 60-day solid oral dosage-form listings, the PBAC recommended retaining Restricted Benefit status but removing indication-specific wording and applying the existing stable-condition clinical criterion. For escitalopram oral liquid, the PBAC recommended retaining Restricted Benefit status, removing indication-specific wording, and adding a criterion requiring that the patient be unable to swallow the solid dosage form.

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Various drugs, strengths, brands, and sponsors Post-market review (Change to existing listings)			The PBAC considered that the changes would better align PBS-subsidised access with contemporary Australian clinical practice, noting that Australian clinical guidelines recommend many of the included antidepressants for conditions beyond their current PBS indications. The PBAC noted that the changes were supported in the pre-PBAC responses received and considered that the changes may reduce inequity for patients for whom out-of-pocket medicine costs are a barrier to treatment. The PBAC noted that broader PBS subsidy arrangements would benefit concessional patients, patients who have reached the annual PBS Safety Net, and eligible First Nations people registered for the Closing the Gap PBS Co-payment Program. The PBAC accepted the Department's modelling approach, including the assumption that all forecast private market utilisation would transition to R/PBS supply, and considered that this provided a conservative basis for estimating the financial impact to the R/PBS. The PBAC considered that the financial impact of the proposed changes was reasonable, noting that the changes would broaden subsidised access across low-cost antidepressants in a therapeutic class associated with high utilisation. The PBAC noted that cost-effectiveness had not been formally established for each broader clinical use, but considered it reasonable to assume that the medicines were likely to represent acceptable value for money, given their existing PBS listing, previous PBAC acceptance as cost-effective, low cost and guideline-supported broader clinical use. The PBAC recommended that the Department monitor utilisation of the included antidepressants following implementation.

Version 2
Amendment
1. RESPIRATORY SYNCYTIAL VIRUS (mRESVIA®)– Sponsor's comment added

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.

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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.