

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING OUTCOMES
DECEMBER 2022 PBAC MEETING**

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

Submission items

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME	
<p>ACALABRUTINIB</p> <p>Capsule 100 mg</p> <p>Calquence®</p> <p>AstraZeneca Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>A resubmission to request a General Schedule Authority Required listing, for use in combination with obinutuzumab, for the treatment of previously untreated CLL or SLL in patients who are unsuitable for fludarabine-based chemoimmunotherapy.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend acalabrutinib, for use in combination with obinutuzumab, for the treatment of patients with previously untreated CLL or SLL, who are considered unsuitable for treatment with fludarabine-based chemoimmunotherapy. The PBAC considered that the claim of superiority versus venetoclax + obinutuzumab was not supported and that a claim of non-inferiority would be more appropriate. As such, the PBAC considered that a cost-minimisation approach would be more appropriate, rather than the cost-utility analysis submitted. The PBAC considered that a substantial price reduction would be required for acalabrutinib + obinutuzumab to be considered acceptably cost-effective.</p> <p><u>Comparator: Venetoclax + obinutuzumab:</u> The PBAC accepted that venetoclax + obinutuzumab, as nominated by the resubmission, was the appropriate comparator.</p> <p><u>Clinical claim: Superior effectiveness and superior safety compared with venetoclax + obinutuzumab:</u> The clinical claim was based on unadjusted unmatched (naïve) indirect comparison and an unanchored matching-adjusted indirect comparison (MAIC) of acalabrutinib + obinutuzumab compared to venetoclax + obinutuzumab for efficacy and safety. The PBAC considered that the evidence presented did not support a claim of superior comparative effectiveness or safety due to differences in patient populations between the trials which did not appear to be adequately accounted for in the MAIC.</p> <p><u>Economic claim: Cost-utility analysis compared with venetoclax + obinutuzumab:</u> The PBAC considered the clinical evidence presented supported a cost-minimisation approach to venetoclax + obinutuzumab.</p> <p><u>Sponsor Comment:</u> The sponsor had no comment.</p>

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<p>IBRUTINIB</p> <p>Capsule 140 mg</p> <p>Imbruvica®</p> <p>Janssen-Cilag Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)</p>	<p>To request a General Schedule Authority Required (Written) listing, for use in combination with venetoclax, for the treatment of previously untreated CLL or SLL.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend ibrutinib, for use in combination with venetoclax, for the treatment of previously untreated CLL or SLL. The PBAC considered the nominated comparator of fludarabine, cyclophosphamide and rituximab (FCR), although of historical relevance, is no longer the therapy most likely to be replaced in clinical practice given its limited use. The PBAC acknowledged that the existing Pharmaceutical Benefits Scheme (PBS) restriction criteria define the patient populations on the basis of treatment with fludarabine being appropriate, however noted the advice from the clinical consultation that these criteria are no longer relevant to clinical practice. The PBAC further noted that, based on the available evidence, it was not possible to determine the magnitude of clinical benefit with ibrutinib + venetoclax versus FCR due to the comparison being based on an unadjusted (naïve) comparison of single arms of different trials, and the limited follow-up of the ibrutinib + venetoclax (CAPTIVATE) trial. Overall, the PBAC considered the comparison presented in the submission versus FCR was not an informative basis for the listing of ibrutinib + venetoclax.</p> <p>Further, following clinical consultation, the PBAC advised that the existing PBS criteria for CLL/SLL treatments be amended as follows:</p> <ul style="list-style-type: none"> • The venetoclax + obinutuzumab restriction for first-line CLL/SLL should be updated to remove the criterion 'inappropriate for fludarabine-based chemoimmunotherapy' and remove reference to the requirement for patients to have a cumulative illness rating scale (CIRS) score > 6 or creatinine clearance < 70 mL/min given the CIRS score was designed to predict toxicity with chemoimmunotherapy rather than targeted agents. • The requirement for patients to be considered unsuitable for treatment or retreatment with a purine analogue should be removed from the restrictions for all PBS listed drugs for CLL/SLL in the relapsed or refractory setting. The PBAC noted this would remove the notes defining this criterion (which include criteria around factors like age and/or CIRS score and del17p). <p><u>Sponsor Comment:</u> Janssen is disappointed that the PBAC has not recommended ibrutinib, for use in combination with venetoclax, for the treatment of previously untreated CLL or SLL. While FCR is not a preferred regimen, FCR is still used in clinical practice and prior to this outcome, the PBS restrictions meant that a significant proportion of younger and fitter patients could only access FCR on the PBS for CLL treatment. Thus, Janssen considers that it was the appropriate comparator for PBAC assessment of this population.</p> <p>Janssen will review the PBAC's feedback and remains committed to finding a way forward to list ibrutinib, in combination with venetoclax, to address a high unmet clinical need for Australians with previously untreated CLL or SLL.</p>
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<p>TIXAGEVIMAB AND CILGAVIMAB</p> <p>Pack containing 1 vial of tixagevimab 150 mg in 1.5 mL and 1 vial of cilgavimab 150 mg in 1.5 mL</p> <p>Evusheld®</p> <p>AstraZeneca Pty Ltd</p> <p>(New PBS listing)</p>	<p>Pre-exposure prevention of COVID-19</p>	<p>A resubmission to request a General Schedule Authority Required listing for pre-exposure prevention of COVID-19 in individuals 12 years or older who are severely immunocompromised due to a specific medical condition or because of treatment with immunosuppressive therapies that render them unlikely to mount an adequate immune response to immunisation.</p>	<p>Not recommended</p>	<p>The PBAC did not recommend the listing of tixagevimab and cilgavimab for use as pre-exposure prophylaxis (PrEP) against COVID-19 infection. The PBAC considered there was a limited clinical place for Evusheld in the current therapeutic landscape. The PBAC considered that the resubmission had not adequately addressed the clinical, economic, financial and risk management issues that had been raised in its September 2022 consideration. Moreover, the emergence and growing prevalence of strains of virus that are likely to be resistant to tixagevimab and cilgavimab since then, increased the uncertainty about the future effectiveness of this treatment for PrEP.</p> <p>The previous submission was considered in September 2022.</p> <p><u>Comparator: Placebo.</u> Consistent with the September 2022 meeting, the PBAC considered that placebo (representative of a no PrEP scenario) was an appropriate main comparator.</p> <p><u>Clinical claim: The resubmission claimed that tixagevimab and cilgavimab provides up to 6 months effectiveness in a vaccinated, immunocompromised cohort. The resubmission did not make any explicit claim in regard to safety.</u></p> <p>Consistent with the September 2022 meeting, the PBAC considered that safety and effectiveness of the proposed dosing regimen tixagevimab 300 mg and cilgavimab 300 mg every 6 months had not been established. The PBAC did not accept that new evidence presented by the resubmission sufficiently supported a 6 month duration of effect.</p> <p><u>Economic claim: cost-effectiveness versus placebo</u></p> <p>The PBAC considered that the modelled cost-effectiveness analysis presented by the resubmission was not adequately justified by clinical evidence. In addition, the analysis did not include any adjustments for potential resistance. The PBAC noted the incremental cost-effectiveness ratio per Quality Adjusted Life Year increases significantly when potential resistance is accounted for in sensitivity analyses.</p> <p><u>Financial estimates</u></p> <p>The PBAC considered there is a significant amount of uncertainty related to the use and ongoing effectiveness of tixagevimab and cilgavimab because of the changing nature of the COVID-19 virus.</p> <p><u>Risk sharing</u></p>

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				<p>The PBAC noted the risks to individuals who have received, or are considering receiving, tixagevimab and cilgavimab for PrEP, arising from the potential resistance of some COVID-19 strains to this therapy and acknowledged the sponsor's commitment to working with the Australian Government and stakeholders to manage this risk.</p> <p>However, the PBAC considered the sponsor's risk management proposal insufficient to address the very significant risks to Government that arise from the uncertainty about the expected size and duration of the future average protective effect of tixagevimab and cilgavimab.</p> <p><u>Sponsor Comment:</u> AstraZeneca is committed to providing continued access to Evusheld for immunocompromised patients at high risk of critical illness from COVID-19 infection. AstraZeneca acknowledges the concerns raised by the PBAC regarding the rapidly changing prevalence mix of sensitive and resistant COVID-19 variants and the subsequent challenges to the cost-effectiveness of Evusheld. We look forward to continuing to work with the Department of Health and Aged Care to ensure access to Evusheld is maintained.</p>
<p>TRASTUZUMAB DERUXTECAN</p> <p>Powder for I.V. infusion 100 mg</p> <p>Enhertu®</p> <p>AstraZeneca Pty Ltd</p> <p>(New PBS listing)</p>	<p>Breast cancer</p>	<p>A resubmission to request a Section 100 (Efficient Funding of Chemotherapy Program) Authority Required (Written) listing for the treatment of human epidermal growth factor receptor 2 (HER2) positive metastatic breast cancer in patients whose disease has progressed following treatment with at least one prior HER2-directed regimen in the metastatic setting or whose disease has progressed during or within 6 months following HER2-directed adjuvant treatment.</p>	<p>Deferred</p>	<p>The PBAC deferred making a recommendation for trastuzumab deruxtecan (T-DXd) for the treatment of HER2 positive metastatic breast cancer for patients who have progressed following a prior HER2 directed therapy for metastatic disease, or relapsed during or within 6 months of receiving adjuvant HER2 directed therapy. In deciding to defer making a recommendation, the PBAC noted that further consultation with the sponsor regarding the cost-effectiveness of T-DXd would be required, along with revised financial estimates.</p> <p><u>Sponsor Comment:</u> The sponsor had no comment.</p>

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Non-submission items

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<p>HUMAN PAPILLOMAVIRUS (HPV) VACCINE ON THE NATIONAL IMMUNISATION PROGRAM (NIP)</p> <p>HUMAN PAPILLOMAVIRUS 9-VALENT VACCINE</p> <p>Injection 0.5 mL pre-filled syringe</p> <p>Gardasil®9</p> <p>Seqirus (Australia) Pty Ltd</p> <p>(Change to listing)</p>	<p>Prevention of infection caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58</p>	<p>To consider a variation to the NIP listing of Gardasil 9 from 2 doses to 1 dose for the adolescent vaccination program and to extend the upper age limit for catch up vaccination.</p>	<p align="center">Recommended</p>	<p>The PBAC recommended a change to the circumstances under which the human papillomavirus 9-valent (9vHPV) vaccine is made available as a designated vaccine for the purposes of the <i>National Health Act 1953</i> based on a request for advice that was initiated by the Chief Medical Officer of the Department of Health and Aged Care. The PBAC recommended that the NIP listing of 9vHPV vaccine be changed from 2 doses to 1 dose for the adolescent vaccination program and that the upper age limit for catch up vaccination be updated from 20 years to 25 years.</p> <p>The PBAC noted the advice of the Australian Technical Advisory Group on Immunisation (ATAGI) regarding the likely non-inferior efficacy of a single dose of 9vHPV vaccine compared to 2 doses in immunocompetent adolescents aligned with recommendations made by the World Health Organization Strategic Advisory Group of Experts on Immunization and the United Kingdom's Joint Committee on Vaccination and Immunisation. The ATAGI recommended that adolescents and adults aged up to 25 years who did not receive HPV vaccination during adolescence be eligible to receive a single dose of 9vHPV vaccine (previously up to age 19 years). The clinical impacts of not proceeding with the schedule change would mean people aged 20 to 25 years, who did not receive a funded HPV vaccine during adolescence, will not be eligible for a funded vaccine.</p> <p>The PBAC noted the dissenting opinion of the sponsor with regards to implementing the proposed change, citing data immaturity and that a hasty move may jeopardise Australia's long-term plans to eliminate HPV. However, the PBAC noted the ATAGI advice and available evidence and was reassured by the long-term immunogenicity studies of single versus multiple doses which demonstrated stabilised geometric mean concentrations out to 11 years.</p>

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				<p>The PBAC advised that on the basis of presented clinical and immunogenicity data, a single dose schedule of 9vHPV is likely to be non-inferior in terms of effectiveness to 2 doses in the currently eligible population (12-19 years) and therefore likely to be cost effective (and cost saving) at the existing unit price of the 9vHPV vaccine. Similarly, the PBAC advised a single dose schedule of 9vHPV is likely to be non-inferior in terms of effectiveness to 2 doses and be cost-effective for immunocompetent individuals from 20-25 years. The PBAC considered that in terms of safety, a single dose of 9vHPV vaccine compared with two doses will likely reduce the number of mild-moderate short term adverse events expected after any vaccine dose.</p> <p>The PBAC acknowledged the public health value of achieving elimination of cervical cancer, and ATAGI's advice that a move to a one dose schedule will need to be supported by prospective monitoring against elimination goals, noting there is moderate residual risk in unvaccinated young people.</p>
<p>MIGALASTAT</p> <p>Capsule containing migalastat hydrochloride 150 mg</p> <p>Galafold®</p> <p>Amicus Therapeutics</p> <p>(New PBS listing)</p>	<p>Fabry disease</p>	<p>To consider the PBS listing of migalastat for the treatment of Fabry disease.</p>	<p>Recommended</p>	<p>In response to a referral from the Life Saving Drugs Program (LSDP) Expert Panel, the PBAC considered the PBS listing of migalastat for the treatment of Fabry disease. The PBAC recommended the Authority Required listing of migalastat on the PBS for the treatment of Fabry disease in patients aged 16 years of age and older who have an amenable mutation. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of migalastat would be acceptable if migalastat was less expensive than the lowest cost enzyme replacement therapy (ERT) on the LSDP for Fabry disease for all patients 16 years of age and older, and that this could be achieved with a cost per patient per year no higher than the cost of ERT for a patient weighing 45 kg. The PBAC acknowledged the importance of patients with Fabry disease having ongoing access to effective therapies.</p>

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<p>RISK OF HERPES ZOSTER INFECTION IN PATIENTS TAKING BIOLOGICS AND JAK INHIBITOR MEDICINES FOR AUTOIMMUNE CONDITIONS</p> <p>Multiple medicines</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>(Post-market Review)</p>	<p>Biologics and JAK inhibitor medicines</p>	<p>For the PBAC to review methods and results of this research.</p>	<p>Noted</p>	<p>The PBAC noted the report on the 'Risk of herpes zoster (HZ) infection in patients taking biologic and janus kinase inhibitor (JAKi) medicines'. The report presented a fully adjusted cohort analysis based on PBS dataset to estimate the risk of HZ in patients using biologic disease-modifying treatments (bDMT) and JAKi. The medicines included in the analysis were those PBS listed for psoriasis, inflammatory bowel disease (IBD), multiple sclerosis and rheumatoid conditions. The report found that the risk of HZ infection was consistently increased with JAKi compared to bDMTs for all mechanisms of action. Patients most at risk of HZ infection were:</p> <ul style="list-style-type: none"> • those who were using JAKi for rheumatoid conditions or IBD; • female patients; • patients with a high number of comorbid conditions • those using concomitant corticosteroids. <p>The PBAC noted that the results were consistent with the results from other studies and supported the publication of this research. The PBAC requested that relevant sponsors be provided with a copy of the report for their information, including GlaxoSmithKline, the sponsor of Shingrix® (a recombinant varicella zoster virus vaccine).</p>

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<p>STOCKTAKE OF PHARMACEUTICAL BENEFITS SCHEME (PBS) SUBSIDISED MEDICINES AVAILABLE FOR ENDOMETRIOSIS AND RELATED CONDITIONS, AND COMPARISON OF CURRENT AUSTRALIAN PHARMACOLOGICAL TREATMENT GUIDELINES</p> <p>Multiple medicines</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>(Post-market Review)</p>	<p>Endometriosis</p>	<p>To provide the PBAC with an overview of medicines available in Australia for use in endometriosis and related conditions according to clinical treatment guidelines and to identify potential gaps between the medicines listed on the PBS and those available via the private market.</p>	<p>Advice provided</p>	<p>The PBAC considered a report on the Stocktake of PBS subsidised medicines available for endometriosis and related conditions (the Report) prepared by the Department. External stakeholders were invited to provide feedback on the report, including on the use and accessibility of medicines for endometriosis available in Australia, for the PBAC's consideration.</p> <p>The PBAC noted the findings of the Report on medicines available for endometriosis and the stakeholder feedback that suggested PBS subsidy of the following medicines, specifically for endometriosis: dienogest, dienogest and estradiol valerate (Qlaira®), non-steroidal anti-inflammatory drugs (NSAIDs), newer generation combined oral contraceptive (COC) pills and medicines used for neuropathic pain.</p> <p>The PBAC noted that the oral progestogen dienogest 2000 mcg is specifically Therapeutic Goods Administration (TGA) registered for endometriosis and its use is supported by clinical guidelines, however the sponsor has not yet made a submission to list their product on the PBS.</p> <p>The PBAC considered the two unrestricted PBS listed NSAIDs (ibuprofen, diclofenac) appropriate to treat endometriosis/pelvic pain without the need to expand the PBS listings of other NSAIDs.</p> <p>The PBAC also considered that expansion of PBS listings for botulinum toxin, diazepam suppositories and neuropathic pain medicines to include treatment of endometriosis was not possible at this time due to the limited evidence base for use in this indication, the risk of off label use and the potential for abuse. The PBAC proposed referring investigation of the effectiveness of these medicines in endometriosis/related conditions to the Medical Research Future Fund for consideration as a research initiative to evaluate the benefits.</p> <p>The PBAC expressed its intention to continue to work with the Department to address the identified issues within its remit to improve access for patients with endometriosis and related conditions to effective PBS subsidised therapies.</p>

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<p>TOCILIZUMAB</p> <p>Injection 162 mg in 0.9 mL single use pre-filled pen</p> <p>Actemra® ACTPen</p> <p>Injection 162 mg in 0.9 mL single use pre-filled syringe</p> <p>Actemra® Subcutaneous Injection</p> <p>Roche Products Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Giant cell arteritis</p>	<p>Consideration of correspondence requesting an amendment to the circumstances under which tocilizumab for giant cell arteritis is available on the PBS.</p>	<p>Recommended</p>	<p>The PBAC recommended to amend the circumstances under which tocilizumab is available on the PBS for giant cell arteritis to include ultrasound in the clinical criteria as a method for diagnosis.</p>

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<p>UTILISATION OF ONDANSETRON FOR JUVENILE IDIOPATHIC ARTHRITIS</p> <p>ONDANSETRON</p> <p>Syrup 4 mg (as hydrochloride dihydrate) per 5 mL, 50 mL Tablet 4 mg (as hydrochloride dihydrate) Tablet 8 mg (as hydrochloride dihydrate) Tablet (orally disintegrating) 4 mg Tablet (orally disintegrating) 8 mg Wafer 4 mg Wafer 8 mg</p> <p>Multiple brands</p> <p>Multiple sponsors</p> <p>(Change to PBS listing)</p>	<p>Antiemetic and anti-nauseant</p>	<p>To consider expanding the PBS listing of ondansetron to allow use in paediatric patients taking methotrexate for the treatment of rheumatic diseases.</p>	<p>Recommended</p>	<p>The PBAC recommended an Authority Required (Streamlined) listing for ondansetron for the treatment of nausea and vomiting associated with cytotoxic chemotherapy (including methotrexate) being used in the treatment of malignancy and juvenile autoimmune conditions. This includes conditions such as juvenile rheumatic diseases as well as uveitis.</p>

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<p>UTILISATION OF SUBCUTANEOUS METHOTREXATE (MTX) FOR JUVENILE IDIOPATHIC ARTHRITIS</p> <p>METHOTREXATE</p> <p>Injection 7.5 mg in 0.15 mL pre-filled syringe Injection 10 mg in 0.2 mL pre-filled syringe Injection 15 mg in 0.3 mL pre-filled syringe Injection 20 mg in 0.4 mL pre-filled syringe Injection 25 mg in 0.5 mL pre-filled syringe</p> <p>Trexject®</p> <p>Link Medical Products Pty Ltd</p> <p>(Change to PBS listing)</p>	<p>Juvenile idiopathic arthritis (JIA)</p>	<p>To consider expanding the PBS listing of MTX to allow use by paediatric patients who have rheumatic diseases.</p>	<p>Recommended</p>	<p>The PBAC recommended expanding the PBS listing of subcutaneous MTX to allow use by patients who have JIA. The PBAC recognised the clinical need for availability of this form of MTX for patients with JIA in the context of significant quality use of medicine issues for patients in whom oral MTX is unsuitable and for whom vial forms present safety concerns for carers and substantial risks of incorrect dosing.</p> <p>The PBAC recommended the JIA listing to have the same authority level (Authority Required (Streamlined)), maximum quantity and repeats as the current PBS listing for severe active rheumatoid arthritis and severe psoriasis.</p>

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Resubmission pathways

<p>*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:</p>	
Standard re-entry	<p>The Standard Re-entry Pathway is the default pathway for resubmissions and also applies where:</p> <ul style="list-style-type: none"> • 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	<p>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.</p>
Early resolution pathway	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
Facilitated resolution pathway	<p>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.</p>