

**PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE (PBAC) MEETING AGENDA
15 DECEMBER 2017 PBAC MEETING**

Closing date for consumer comments 14 November 2017

The PBAC agenda primarily consists of applications relating to the new listing of a drug or vaccine on the PBS or the National Immunisation Program.

The PBAC agenda consists of the following:

- 1 Minutes of Previous Meeting**
- 2 Chairman's report (verbal)**
- 3 Matters arising from the minutes**
- 4 Matters arising/outstanding**
- 5 New drug applications**
- 6 Requests for changes to listings**
- 7 Resubmissions**
- 8 Pricing Matters**
- 9 Matters relating to PBS review**
- 10 Subcommittee and Working Party reports**
- 11 Other business**
- 12 Correspondence**
- 13 Further information**
- 14 Late papers**
- 15 Tabled papers**

Consumers will have the opportunity to provide comments on new drug submissions (item 5), changes to listings (item 6) and resubmissions (item 7). In many circumstances, consumers will be able to comment on items in other sections of the agenda. The submissions for which input is sought will be listed in alphabetical order by drug name. There is no provision for consumer comments to the PBAC on agenda item 8 which relates to pricing matters.

Pharmaceutical benefits listed in the Schedule fall into three broad categories:

Unrestricted benefits – have no restrictions on their therapeutic uses;

Restricted benefits – can only be prescribed for specific therapeutic uses (noted as Restricted benefit); and

Authority required benefits – Authority required benefits fall into two categories:

- *Authority required benefits* require prior approval from Medicare Australia or the DVA (noted as Authority required)
- *Authority required (STREAMLINED) benefits* do not require prior approval from Medicare Australia or the DVA but require the recording of a streamlined authority code (noted as Authority required (STREAMLINED)).

Submissions are categorised broadly as major or minor:

- *Major*: Submissions to list new medicines on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are generally classified as major submissions. Major submissions require presentation of an economic evaluation.
- *Minor*: Submissions that relate to new forms of previously listed products and changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. Minor submissions do not usually require the presentation of an economic evaluation.

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Submission type (new listing, change to listing)	Drug Name, form(s), strength(s) and Sponsor (Drug name, form, strength, Trade name®, Sponsor)	Drug Type and Use (What is the drug used to treat?)	Listing requested by Sponsor / Purpose of Submission (Includes type of listing requested (unrestricted, restricted benefit, authority required) and restriction wording. If restriction is lengthy it may be paraphrased.)
New listing (Major Submission)	ADALIMUMAB Injection 40 mg in 0.4 mL pre-filled syringe Injection 40 mg in 0.4 mL pre-filled pen Humira® AbbVie Pty Ltd	All current subsidised indications of adalimumab on the PBS	To request Authority Required listings for an alternative formulation of adalimumab, for all existing PBS subsidised indications.
New listing (Major Submission)	CABOZANTINIB Tablet 20 mg Cabometyx® Ipsen Pty Ltd	Clear cell variant renal cell carcinoma (RCC)	To request an Authority Required (STREAMLINED) listing for the treatment of Stage IV clear cell variant RCC in patients previously treated with a tyrosine kinase inhibitor (TKI).
Change to listing (Major Submission)	EVEROLIMUS Tablet, dispersible, 2 mg Tablet, dispersible, 3 mg Tablet, dispersible, 5 mg Afinitor® Novartis Pharmaceuticals Australia	Tuberous sclerosis complex	To request an Authority Required listing for the treatment of patients with refractory seizures associated with tuberous sclerosis complex in combination with other anti-epileptic medications.
New listing (Major Submission)	FLUTICASONE FUROATE WITH UMECLIDINIUM AND VILANTEROL Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenate) per dose	Chronic obstructive pulmonary disease (COPD)	To request an Authority Required (STREAMLINED) listing for the treatment of patients with moderate to severe COPD (FEV<50% predicted) and frequent exacerbations despite regular maintenance treatment.

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	<p>Trelegy® Ellipta®</p> <p>GlaxoSmithKline Australia Pty Ltd</p>		
<p>New listing</p> <p>(Major Submission)</p>	<p>ROMIDEPSIN</p> <p>Powder for I.V. infusion 10 mg</p> <p>Istodax®</p> <p>Celgene Pty Ltd</p>	<p>Relapsed or refractory peripheral T-Cell lymphoma (PTCL)</p>	<p>Resubmission to request a Section 100 (Efficient Funding of Chemotherapy) Authority Required listing for the treatment of relapsed or refractory PTCL.</p>
<p>Change to listing</p> <p>(Consideration following deferral)</p>	<p>TENOFOVIR with EMTRICITABINE</p> <p>Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg</p> <p>Truvada®</p> <p>Gilead Sciences Pty Ltd</p> <p>Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg</p> <p>Tenofovir Disoproxil Emtricitabine Mylan 300/200®</p> <p>Alphapharm Pty Ltd (trading as Mylan Australia)</p>	<p>Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)</p>	<p>To provide the PBAC with additional economic analyses and utilisation scenarios prepared by the Kirby Institute, as requested by the PBAC when it deferred the submissions for PrEP at its July 2017 meeting.</p>

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Change to listing (Minor submission)	TENOFOVIR with EMTRICITABINE Tablet containing tenofovir disoproxil phosphate 291 mg with emtricitabine 200 mg Tenofovir EMT GH® Generic Health Pty Ltd	Human immunodeficiency virus (HIV) pre-exposure prophylaxis (PrEP)	To request an Authority Required (STREAMLINED) listing for PrEP in the context of the cost-effectiveness parameters under the consideration of the PBAC following its deferral of PrEP at the July 2017 meeting.