

**6.16 TENOFOVIR with EMTRICITABINE,  
Tablet containing tenofovir disoproxil maleate 300 mg  
with emtricitabine 200 mg,  
Tenofovir Disoproxil Emtricitabine Mylan 300/200<sup>®</sup>,  
Alphapharm Pty Ltd**

**1 Purpose of Application**

- 1.1 The minor submission requested listing of tenofovir (as disoproxil maleate) with emtricitabine for pre-exposure prophylaxis (PrEP) against HIV infection.
- 1.2 The PBAC noted the Department's advice that, subject to the approval of the Minister (delegate) the Alphapharm brand of tenofovir with emtricitabine was PBS listed for the treatment of HIV infection on 1 August 2017. This application seeks to extend that listing at a future date to include PrEP.

**2 Requested listing**

- 2.1 The submission did not propose a restriction.
- 2.2 The PBAC advised that its preferred listing for tenofovir with emtricitabine for PrEP would incorporate the following:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
TENOFOVIR DISOPROXIL MALEATE 300 MG + EMTRICITABINE 200 MG ORAL TABLET, 30	1	2		Tenofovir Disoproxil Emtricitabine Mylan 300/200® Alphapharm Pty Ltd
Category / Program:	General Schedule			
PBS Indication:	Pre-exposure prophylaxis against HIV in adults at medium to high risk of infection			
Restriction:	Streamlined			
Treatment criteria:				
Clinical criteria:	Patient must be at high risk of HIV infection AND Patient must return a negative HIV test prior to initiating treatment AND Patient must continue to return negative HIV tests at 3 monthly intervals throughout treatment.			
Population criteria:	Patient must be 18 years or older			
Category / Program:	General Schedule			

- 2.3 The PBAC considered that tenofovir with emtricitabine for PrEP should be listed as a General Schedule item to ensure widest access and should include provision for nurse-practitioner prescribing.
- 2.4 The Secretariat noted that there may be State or Territory restrictions on prescribing of tenofovir with emtricitabine. The effect of those restrictions, if any, on access to PrEP will need to be further investigated if tenofovir with emtricitabine is recommended for listing for this indication. The Department will work with the States and Territories on this issue.
- 2.5 The report commissioned by the Australian Federation of AIDS Organisations (AFAO)<sup>1</sup> (provided as a reference with the minor submission) included the risk criteria for men who have sex with men (MSM) to identify their eligibility for PrEP from the draft 2017 Australasian Society for HIV Medicine (ASHM) Clinical Guidelines. These are presented in Table 1. The draft guidelines are also noted to recommend PrEP in heterosexual people and injecting drugs users in limited circumstances.

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<sup>1</sup> Kirby Institute and the Centre for Social Research in Health (February 2017). Discussion paper: Estimates of the number of people eligible for PrEP in Australia, and related cost-effectiveness, Prepared for the Australian federation of AIDS Organisations (AFAO)

**Table 1: Draft Risk criteria for MSM to identify their eligibility for PrEP**

<b>A. High risk – recommend prescribing daily PrEP if the patient acknowledges</b>		
Having had any of the following in the last 3 months: <ul style="list-style-type: none"> <li>At least one episode of condomless anal intercourse (CLAI) with a regular HIV+ partner (not on treatment and/or detectable viral load)</li> <li>At least one episode of receptive CLAI with any casual HIV + male partner or a male partner of unknown status</li> <li>Rectal gonorrhoea, rectal chlamydia or infectious syphilis diagnosis (during the last 3 months or at screening for PrEP)</li> <li>Methamphetamine use, which may increase the risk of HIV acquisition</li> </ul>	AND	Being likely to have in the next 3 months (indicating sustained risk): <ul style="list-style-type: none"> <li>Multiple events of CLAI, with or without sharing intravenous drug equipment</li> </ul>
<b>B. Medium risk – consider prescribing daily PrEP, based on case by case approach if discussion reveals</b>		
Having had any of the following in the last 3 months <ul style="list-style-type: none"> <li>More than one episode of anal intercourse when proper condom use was not achieved (e.g. condom slipped off or broke) where the serostatus of partner was no known, or was HIV+ and not on treatment with a detectable viral load</li> <li>(if patient uncircumcised) more than one episode of insertive CLAI where the serostatus of partner was not known, or was HIV + and not on treatment or with a detectable viral load</li> </ul>	AND	Being likely to have in the next 3 months (indicating sustained risk) <ul style="list-style-type: none"> <li>Multiple events of CLAI, with or without sharing intravenous drug equipment</li> </ul>
<p><b>Case by case approach</b></p> <p>Based on a complete sexual and alcohol and other drug-using history and the personal circumstances of the patient, if the clinician is of the opinion that the patient is likely to be at high risk of HIV, then PrEP prescription may be considered despite the absence of reported high- or medium-risk factors above.</p>		

Source: Wright, Edwina, et al. Australasian Society for HIV, Viral Hepatitis, and Sexual Health Medicine - HIV Pre-Exposure Prophylaxis: clinical guidelines. Journal of Virus Eradication, 2017; 3: 168-184. Accessed 5 July 2017. Open access, available at [http://viruseradication.com/journal-details/Australasian\\_Society\\_for\\_HIV,\\_Viral\\_Hepatitis\\_and\\_Sexual\\_Health\\_Medicine\\_HIV\\_pre-exposure\\_prophylaxis:\\_clinical\\_guidelines/](http://viruseradication.com/journal-details/Australasian_Society_for_HIV,_Viral_Hepatitis_and_Sexual_Health_Medicine_HIV_pre-exposure_prophylaxis:_clinical_guidelines/)

2.6 The PBAC considered it appropriate for the eligible population to include medium and high risk individuals as defined the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM) Guidelines, including people who share injecting equipment, noting that the ASHM Guidelines have now been finalised.

2.7 The PBAC considered that the proposed maximum quantity and number of repeats which provides for up to 3 months' treatment is appropriate and reflects the need for frequent review of patient circumstances, including their risk profile and HIV infection status. The PBAC noted the increase in the reported cases of sexually transmitted infections (STIs) in the clinical studies of PrEP and considered in clinical practice the requirement of a medical practitioner visit every 3 months to obtain a prescription for TDF/FTC is likely to increase monitoring for STIs and result in earlier diagnosis.

2.8 The sponsor requested a separate PBS item code for the PrEP indication, to distinguish it from the treatment indication, [REDACTED]

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*For more detail on PBAC’s view, see section 5 “PBAC outcome.”*

### **3 Background**

- 3.1 The Tenofovir Disoproxil Emtricitabine Mylan 300/200<sup>®</sup> brand of tenofovir with emtricitabine was TGA registered on 10 April 2017 and is indicated for:
- the treatment of HIV infected adults over the age of 18 years, in combination with other antiretroviral agents; and
  - in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk.
- 3.2 This brand of tenofovir with emtricitabine has not been previously considered by the PBAC. As noted above, this brand of tenofovir with emtricitabine was PBS listed for the treatment of HIV infection on 1 August 2017.
- 3.3 Tenofovir with emtricitabine (Truvada<sup>®</sup>, marketed by Gilead Sciences Pty Ltd) was previously considered for the PrEP indication at the July 2016 PBAC meeting, and was rejected on the basis that<sup>2</sup>:
- There was unacceptable and uncertain cost-effectiveness in the proposed population at the proposed price.
  - Attempts to severely restrict the eligible population based on individual risk calculation in the submission may not have been feasible, appropriate or acceptable to clinicians and consumers.
  - The PBAC considered it may be more appropriate for a broader group of individuals to have access to PrEP than proposed in the submission.
  - The PBAC considered that the available data were not representative of the proposed population. The Committee’s concerns about the applicability of the trial data to the Australian setting included that a large proportion of the data were generated in communities known to have a substantially higher incidence of HIV infection (and therefore higher risk) than the Australian population.
  - The PBAC was uncertain if other safe sex practices would be utilised to the same extent in the Australian population, and how this would change over time, and noted reduced condom use had been reported with the Vic PrEP and PrELUDE Australian PrEP demonstration studies.
  - The PBAC considered that the economic models presented likely overestimated the efficacy of Truvada<sup>®</sup> and that the economic models lacked face validity and

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<sup>2</sup> Tenofovir with emtricitabine (Truvada<sup>®</sup>) Public Summary document, pp 21-22

were biased towards underestimating future need.

- 3.4 On the basis of Gilead’s July 2016 submission, the PBAC considered that PrEP could reduce the risk of acquiring HIV when used in combination with safer sex practices and regular HIV testing, but as a strategy PrEP was not always effective in preventing the acquisition of the virus. The PBAC noted that the efficacy of tenofovir with emtricitabine was highly dependent on adherence.
- 3.5 Gilead Sciences Pty Ltd made a major resubmission for Truvada® for PrEP for review at the July 2017 PBAC meeting.
- 3.6 Representatives from the Department of Health, pharmaceutical industry, clinical organisations and other groups attended a roundtable discussion on approaches to PrEP in February 2017. At the meeting, a report commissioned by the Australian Federation of AIDS Organisations (AFAO) (and undertaken by the Kirby Institute and the Centre for Social Research in Health) was presented which provided a new economic model and utilisation estimates for tenofovir disoproxil with emtricitabine for PrEP. A copy of the report (dated February 2017) was provided with the minor submission. As part of the PBAC evaluation process, PBAC members and evaluators met with the developers of the Kirby model to examine the model consistent with the usual examination of sponsor developed models.

**Committee in confidence information**



**End committee in confidence information**

**Drug cost/patient/year: \$** [redacted]

- 3.7 The proposed approved ex-manufacturer price (AEMP) is \$ [redacted], which after applying the relevant mark-ups and dispensing fees for a general schedule listing, results in a DPMQ of \$ [redacted]. The drug cost per patient per year was calculated based on the proposed DPMQ with 12 prescriptions per year, and will be \$ [redacted] at listing.
- 3.8 The submission notes that tenofovir disoproxil with emtricitabine 300/200 will be subject to price disclosure from 1 August 2017. The submission estimates that the AEMP will reduce over time as outlined in Table 2. The mark-ups and fees used to calculate the DPMQs are those current as at 1 June 2017.

Table 2: Estimated impact of price disclosure on AEMP and DPMQ for tenofovir disoproxil with emtricitabine

	Dec-17	Oct-18	Oct-19	Oct-20	Apr-21	Apr-22
AEMP	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
General Schedule DPMQ	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]

## Economic Analysis

3.9 A description of the economic model developed by the Kirby Institute is provided in the AFAO report submitted with the minor application. In summary:

- The Kirby model assessed the cost-effectiveness of PrEP in MSM using a HIV transmission model. The model partitions the overall Australian population by population group and by HIV health state. HIV infections occur through the interaction between different populations by regular, casual, or commercial (including transactional) sexual partnerships, or through sharing of injecting equipment.
- The rate that uninfected individuals become infected depends on the number and type of risk events (such as condomless sexual intercourse or sharing of syringes) to which individuals are exposed in a given period and the infection probability of each event.
- The model was calibrated using Australian data on HIV infections for 2000-2015 for population subgroups, and then predicted the number of infections for 2016-2030. PrEP usage was considered separately for MSM at high, medium and low risk of HIV infection. The estimated number (%) of high, medium and low risk MSM in 2015 was 38,200 (28.2%), 5,100 (4%) and 80,300 (67.8%), respectively.

3.10 The key model assumptions were:

- An annual cost for tenofovir with emtricitabine of \$9,605 (based on the PBS cost for treatment of HIV). The annual cost proposed in this minor submission for tenofovir with emtricitabine for PrEP is \$ [REDACTED] (general schedule).
- The assumed coverage of PrEP would be reached by year 3. The time required to reach the assumed coverage levels was based on experience from the Australian demonstration programs.
- PrEP would be associated with 90% adherence resulting in 99% efficacy. These estimates were stated to be based on emerging evidence from the Australian demonstration projects and the PRELUDE PrEP study.
- No reduction in the use of condoms with PrEP. The impact of reduced condom use on HIV infection was tested in sensitivity analyses. The impact of reduced condom use on the incidence of other sexually transmitted diseases (STIs) was not assessed in the model.

3.11 The model inputs are summarised in Sections 4-6 of the AFAO report.

3.12 The results for the Kirby model are presented for a number of scenarios based on



30% across the three risk strata was considered to reflect the maximum realistic coverage. The ASHM guidelines do not recommend the use of PrEP in adults considered to be at low risk of HIV infection however, in practice there may be some use in these individuals as the criteria for assessing risk are based on reported behaviour. The use of PrEP in low risk individuals is substantially less cost-effective than in medium and high risk patients. The use of PrEP in medium risk individuals has only a small impact on the cost-effectiveness of PrEP as MSM at medium risk are estimated to make up only 4% of the total MSM population.

- 3.15 Based on the proposed annual PrEP cost of \$██████ in the minor submission, the cost per QALY gained would be less than \$15,000 - \$45,000 if uptake was restricted to high risk MSM and the uptake does not exceed approximately ██████%.
- 3.16 For the scenario 90-60-30 (the maximum realistic coverage), the annual PrEP cost would need to be \$2,150 for the cost per QALY gained to be \$30,000. If the use in low risk MSM is removed (Scenario 90-60-0), the annual PrEP cost would need to be \$3,730 for the cost per QALY gained to be \$30,000.
- 3.17 Sensitivity analyses were undertaken assessing the impact of adherence on the cost-effectiveness of PrEP. A reduction in adherence leads to improved cost-effectiveness of PrEP. This reflects the assumptions regarding relatively high efficacy with a reduction in the number of doses per week (99% efficacy for 7 doses per week, 96% for 4 doses per week and 76% for 2 doses per week) that is associated with a reduction in the costs of drug use. Intermittent use of PrEP was not considered. Individuals may cease PrEP, and possibly restart at a separate time as their circumstances change.

#### ***Estimated PBS usage & financial implications***

- 3.18 The submission's utilisation estimates were based on the MSM population at high risk of HIV infection. The AFAO report (p7) estimated the MSM population at high risk to be 31,502 individuals.

**Committee in Confidence Information**

[Redacted content]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted content]

**End Committee in Confidence Information**

3.19 The submission’s estimates assumed an uptake rate of █% in year 1, increasing to █% in year 5 and 12 prescriptions dispensed per year. At year 5, the submission estimated a total use of █ prescriptions, at a cost to government (at the proposed ex-manufacturer price) of approximately \$█. A summary of the utilisation and financial estimates are presented in Table 4.

**Table 4: Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5
Number of patients eligible (MSM at high risk of HIV infection, based on Kirby Report figures)	31,502	31,502	31,502	31,502	31,502
Uptake rate	█%	█%	█%	█%	█%
Number of patients treated	█	█	█	█	█
Number of prescriptions (based on 12 scripts per patient per year)	█	█	█	█	█
Cost at proposed AEMP (\$358.29)	\$█	\$█	\$█	\$█	\$█
Cost at proposed DPMQ (\$402.97)	\$█	\$█	\$█	\$█	\$█

Source: Pricing table, p 4 of the submission, amended to include estimates at DPMQ. Abbreviations: MSM, men who have sex with men; HIV, human immunodeficiency virus; AEMP, approved ex-manufacturer price; DPMQ, dispensed price for maximum quantity.

3.20 The AFAO Report/Kirby Model provided a range of scenarios of PrEP uptake in high, medium and low risk populations, which do not directly correlate with the estimates provided in the submission. In its full model, Kirby estimated populations stratified

by risk profile, and relied on a different high risk estimate of the eligible PrEP population. The high risk population was estimated at 28.2% of all HIV negative gay men, the medium risk population at 4% of all HIV negative gay men, and the low risk population at 67.8% of all HIV negative gay men. Table 5 below presents utilisation estimates and uptake scenarios from the AFAO Report/Kirby Model using the prices (AEMP and DPMQ) proposed by the sponsor. The below estimates assume a constant underlying population eligible for PrEP and that all individuals receive 12 prescriptions per year. The listing proposed by the Secretariat requires patients be reassessed for eligibility for PrEP every 3 months. It is likely that patients will cease PrEP (and possibly restart at a separate time) as their circumstances change. This has not been considered in the estimates below.

**Table 5: Estimated use and financial implications based on AFAO Report/Kirby model at proposed DPMQ, without predicted price disclosure cycles**

	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Eligible population estimates</b>					
Number of patients defined as high risk (AFAO Report, p 7)	38,200	38,200	38,200	38,200	38,200
Number of patients defined as medium risk (AFAO Report)	5,100	5,100	5,100	5,100	5,100
Number of patients defined as low risk (AFAO Report)	80,300	80,300	80,300	80,300	80,300
<b>Uptake scenarios</b>	<b>Number of patients receiving PrEP</b>				
Scenario 30-0-0	11,460	11,460	11,460	11,460	11,460
Scenario 60-0-0	22,920	22,920	22,920	22,920	22,920
Scenario 90-0-0	34,380	34,380	34,380	34,380	34,380
Scenario 90-20-0	35,400	35,400	35,400	35,400	35,400
Scenario 90-60-0	37,440	37,440	37,440	37,440	37,440
Scenario 90-20-10	43,430	43,430	43,430	43,430	43,430
Scenario 90-60-30	61,530	61,530	61,530	61,530	61,530
Scenario 90-90-90	111,240	111,240	111,240	111,240	111,240
<b>Scenario cost at DPMQ (\$402.97) (assumes 12 scripts p.y.)</b>	<b>Cost to PBS/RPBS</b>				
Scenario 30-0-0	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 60-0-0	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-0-0	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-20-0	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-60-0	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-20-10	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-60-30	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████
Scenario 90-90-90	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████	\$ ██████████

3.21 For the scenario 90-60-30 (the maximum realistic coverage), the cost to the PBS/RPBS would be \$ ██████████ per year at the proposed initial list price. If the use in low risk MSM is excluded (Scenario 90-60-0), the cost to the PBS/RPBS would be \$ ██████████ per year.

3.22 For the scenario 60-0-0, the cost to the PBS/RPBS would be \$ ██████████ per year.

*For more detail on PBAC’s view, see section 5 “PBAC outcome.”*

## 4 Consideration of the evidence

### *Sponsor hearing*

4.1 There was no hearing for this item as it was a minor submission.

### *Consumer comments*

4.2 The PBAC noted and welcomed the input from individuals (3), and organisations (10) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of TDF/FTC as PrEP, including greater protection from HIV, positive changes in community perceptions of HIV, and a reduction in stigma for those living with HIV. The PBAC noted the consumer comments submitted from a social media based support group “PrEP’D For Change” which also described the benefits of PrEP and the current legal and financial challenges for patients accessing PrEP via the TGA Personal Importation Scheme.

4.3 The PBAC noted advice received from the Australian Federation of AIDS Organisations (AFAO) and National Association of People with HIV Australia (NAPWHA), which described the benefits of PrEP, including data from the IPERGAY trial which reported an 86% reduction in the risk of HIV infection among participants, and further described the efficacy of PrEP in a ‘real-world’ setting, and associated health benefits such as more frequent sexual health checks and patient contact with clinicians. The PBAC noted the AFAO was supportive of a General Schedule PBS listing.

4.4 The PBAC also noted the correspondence of support for the AFAO position from the following organisations:

- AIDS Council of NSW (ACON)
- AIDS Action Council of the ACT
- The Bobby Goldsmith Foundation
- Family Planning NSW
- Multicultural HIV and Hepatitis Service NSW
- Victorian AIDS Council
- Western Australian AIDS Council

## 5 PBAC Outcome

- 5.1 The PBAC deferred making a recommendation on tenofovir with emtricitabine for HIV Pre-exposure Prophylaxis (PrEP) to seek additional results for the cost-effectiveness model developed by the Kirby Institute. Specifically the Committee requested additional analyses considering alternative uptake scenarios where the extent of uptake is reduced and use is limited to medium and high risk individuals, and for sensitivity analyses varying the tenofovir with emtricitabine price.
- 5.2 In making this recommendation, the PBAC noted the significant price reduction offered by Alphapharm compared to the current PBS price for tenofovir with emtricitabine for treatment of HIV. However, based on the proposed annual PrEP cost of \$██████ in the submission, the cost per QALY gained would not be less than \$30,000 unless uptake was restricted to high risk MSM and the uptake does not exceed approximately ██████%. For the scenario 90-60-30 (the maximum realistic coverage), the annual PrEP cost would need to be \$2,150 for the cost per QALY gained to be \$30,000. If the use in low risk MSM is removed (Scenario 90-60-0), the annual PrEP cost would need to be \$3,730 for the cost per QALY gained to be \$30,000.
- 5.3 The PBAC noted the results for the Kirby model were presented for a number of scenarios based on different uptake in individuals at high, medium or low risk of infection. The uptake scenarios ranged from 30-0-0 (30% uptake in high risk, 0% in medium risk, 0% in low risk; 8.4% overall uptake) to 90-90-90 (90% overall uptake). The PBAC noted that only two of the scenarios presented considered use in individuals at high and medium risk of infection, the population which the PBAC agreed to be appropriate. Further, both of the scenarios assumed 90% uptake in high risk individuals and the PBAC considered that this level of uptake was unlikely to be achieved in clinical practice. The PBAC considered alternative scenarios assuming lower uptake in medium and high risk individuals would be informative.
- 5.4 The PBAC further requested sensitivity analyses varying the TDF/FTC price to be undertaken for these additional scenarios. The PBAC recalled that the threshold of incremental QALYs gained for treatments with large opportunity costs, such as population preventative interventions including lipid-lowering, anti-hypertensive drugs and vaccines was at the lower end of the ICER range that PBAC has accepted because these treatments typically have a high opportunity cost. Though not completely analogous to a vaccination program such as against Human Papillomavirus (HPV), the PBAC considered that subsidisation of PrEP, like the HPV vaccine, would provide both direct benefits to the treated individual and wider benefits to society with reductions in the prevalence of HIV infection over time. The PBAC considered that the acceptable ICER/QALY for PrEP should be at the low end of

the range previously accepted for these other population preventative interventions with large opportunity costs.

- 5.5 The PBAC considered the utilisation estimates were highly uncertain and difficult to predict, however utilisation was likely overestimated in years 2-5.
- 5.6 The PBAC noted that, depending on the further information being sought, there may be considerable uncertainties associated with the cost effective usage of this drug and consideration should be given to how to best manage those uncertainties if a recommendation is made for a PBS listing in future.
- 5.7 The PBAC noted that this submission is not eligible for an Independent Review as it was deferred.

**Outcome:**

Deferred

## **6 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## **7 Sponsor's Comment**

The sponsor had no comment.