3.02 DUPILUMAB

Injection 200 mg in 1.14 mL single dose pre-filled syringe,
Injection 300 mg in 2 mL single dose pre-filled syringe
Dupixent®,
Sanofi-Aventis Australia Pty Ltd

1 Purpose of Application

1.1 Dupilumab for the treatment of patients aged 12 years and older with severe atopic dermatitis (AD) who are inadequately controlled on topical therapies was recommended at the March 2020 PBAC meeting.

1.2 Following the recommendation, the sponsor submitted pricing proposals to the Department, which were not accepted, as they were not consistent with the PBAC advice. Primarily, after the sponsor's adjustment to the economic model, the resulting ICER was higher than the range considered by the PBAC.

1.3 The sponsor requested the PBAC's consideration of its latest proposal which presents:

- Revised inputs to the economic model and a new base case ICER; and
- Revised inputs to the financial estimates, including alternate uptake rates applied using a different approach to that specified in the PBAC minutes.

2 Background

Previous PBAC consideration

2.1 Dupilumab was previously considered for this indication by the PBAC in July 2018, July 2019, and recommended at its March 2020 meeting.

2.2 A summary of the March 2020 PBAC consideration and current proposal is provided in the table below.

Table 1: Summary of the March 2020 PBAC consideration and current proposal

	March 2020 PBAC consideration	**Current proposal**
Requested effective DPMQ	$[redacted]	$[redacted]
Economic evaluation		
Extent of use of phototherapy	…the PBAC agreed with the ESC that the magnitude of cost offsets from phototherapy applied in the model was not reasonable, particularly as the model included no effectiveness from phototherapy utilisation (paragraph 7.15, Dupilumab PSD, March 2020 PBAC Meeting).	Number of phototherapy treatments per week reduced in the economic model from 3.0 to 2.0.
Maintenance of response	The PBAC noted a differential maintenance of response for dupilumab and SoC was assumed in the economic model. The pre-PBAC response argued, rather than applying the same relative reduction to the response rates over time (as had been done in the evaluation), that the same absolute reduction should be applied. (paragraph 7.16, Dupilumab ratified PSD, March 2020 PBAC Meeting).	Maintenance of response in the revised economic model is based on use of the same absolute reduction over time as presented in the March 2020 pre-PBAC response.
Medical resource unit costs	As per submission.	Unit costs for medical resource utilisation updated in economic model to reflect 2020 costs (see Table 6 of sponsor's proposal).
ICER	Overall in relation to the cost-effectiveness of dupilumab, the PBAC noted the base case ICERs presented in the resubmission were $[redacted][1]/QALY for the CsA-naive[a] population and $[redacted][2]/QALY for the CsA-experienced[a] population. The PBAC considered the ICERs to be underestimated due to overestimating the extent of phototherapy use and the submission's assumptions regarding maintenance of response. The PBAC considered that the effective price for dupilumab should be reduced to address the likely underestimation of the ICER (paragraph 7.17, Dupilumab PSD, March 2020 PBAC Meeting).	ICERs for economic model with revised effective price, use of phototherapy, maintenance of response and medical resource unit costs: • $[redacted][2]/QALY for CsA-naïve • $[redacted][3]/QALY for CsA-experience

	March 2020 PBAC consideration	Current proposal
Estimated net cost to PBS		
Addition of adolescent population	The PBAC noted the financial estimates would need to be revised to include patients aged 12-17 years. The PBAC noted that the population size increases by approximately 9%. The PBAC noted that a reduced dose (200 mg every other week) is recommended in patients aged 12-17 years with a body weight of <60 kg and considered the reduced dose should be accounted for in the financial estimates (paragraph 7.18, Dupilumab PSD, March 2020 PBAC Meeting).	Adolescent (12-17 year olds) population and 200 mg dose included.
Proportion of topical corticosteroid (TCS) therapy patients who have uncontrolled AD	This was estimated to be 68% in the March 2020 resubmission. During the evaluation of the March 2020 resubmission it was stated that it was inappropriate to have assumed some severe AD patients would be 'adequately controlled' on treatment. It was also stated in the evaluation that this is a major source of uncertainty in the financial estimates and may underestimate the eligible patients (Table 19, Dupilumab PSD, March 2020 PBAC Meeting). The PBAC did not recommend revisions to this input; recommended revisions are noted in paragraph 7.17 of the March 2020 PSD.	Assumed 100% of patients on TCS therapy would have uncontrolled AD.
Uptake rates applied to prevalent patient pool	The PBAC noted that the uptake rates of 5% in year 1, increasing to 7.5% in year 6 were applied to the prevalent pool of eligible patients each year to calculate the number of patients initiating treatment. When continuing patients are taken into account the overall uptake is higher, and by year 6 continuing patients represent 14% of the eligible patients (6,036/44,248). The PBAC considered that it was reasonable that the overall uptake of dupilumab would increase in each year, accounting for both new and continuing patients. However, the PBAC considered it is not reasonable to assume the uptake rate of new patients from the prevalent pool would increase each year. The PBAC considered that the uptake rates of 5.5% in year 2, increasing to 7.5% in year 6 should be applied such that they reflect the proportion of continuing patients in each year (e.g. 3,319 continuing patients in year 6 is 7.5% (3,319/44,248) of the eligible patients) (paragraph 6.56, Dupilumab ratified PSD, March 2020 PBAC Meeting).	Revised uptake rates based on PBS uptake of biologic therapies for ankylosing spondylitis, psoriasis and Crohn disease. <u>Uptake rates (years 1-6) applied to prevalent pool of patients</u> March 2020 submission: 5%, 5.5%, 6.0%, 6.5%, 7.0%, 7.5% March 2020 PBAC recommendation: 5%, 4.2%, 2.7%, 2.5%, 2.6%, 2.7% Pricing proposal (as per sponsor's clarification in pre-PBAC response): 5%, 4.50%, 4.0%, 3.5%, 3.5%, 3.5%

	March 2020 PBAC consideration	Current proposal
MBS phototherapy cost offsets	The PBAC considered that overall phototherapy services are unlikely to be reduced as a result of listing dupilumab as they are largely at capacity and therefore should not be included as cost-offsets in the financial estimates (paragraph 7.19, Dupilumab PSD, March 2020 PBAC Meeting).	The cost offset of phototherapy has been removed from the calculated net changes to the MBS budget in the utilisation estimates workbook.
Risk sharing arrangement	The PBAC considered the potential for use of dupilumab outside the proposed restriction could be managed through a risk sharing arrangement (paragraph 7.1, Dupilumab PSD, March 2020 PBAC Meeting).	Sponsor agrees in principle to the March 2020 recommendation regarding the proposed details of the RSA.

[a] CsA-naïve and CsA-experienced erroneously switched in March 2020 PBAC PSD= public summary document
The redacted values correspond to the following ranges:
[1]$45,000 to <$55,000/QALY gained
[2]$25,000 to <$35,000/QALY gained
[3]$35,000 to <$45,000/QALY gained

3 Requested listing

3.1 There are no requested changes to the March 2020 recommended listing.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted and welcomed the input from individuals (71) and organisations (2) via the Consumer Comments facility on the PBS website, and recalled the significant consumer input previously received in relation to the March 2020 consideration of dupilumab. The comments described the significant disease burden and impact on quality of life associated with severe eczema and the range of potential benefits of treatment with dupilumab including improvements in itch, pain, sleep, mental health and ability to work and study.

4.3 The PBAC noted the advice received from the Eczema Association of Australia Inc and Eczema Support Australia that strongly supported the listing of dupilumab and highlighted the urgent need for a new treatment option for this condition that has significant physical, emotional and financial impacts on patients.

Economic analysis

4.4 The sponsor's proposal makes the following adjustments to the base case economic model considered at the March 2020 meeting:

- Reduction in phototherapy use from 3 to 2 treatments per week;

- Revised maintenance of response using the approach outlined in the pre-PBAC response for the March 2020 resubmission such that the absolute reduction in response estimated for dupilumab in year 2 was also applied to the comparator (standard of care); and
- Updated medical resource costs to 2020 values.

4.5 The adjustments to the model described above, and the reduced proposed DPMQ of $[redacted], resulted in an ICER of $45,000 to <$55,000/QALY for CsA-naïve patients (Table 2) and $35,000 to <$45,000/QALY for CsA-experienced patients. This is higher than the ICERs considered by the PBAC in March 2020 ($45,000 to <$55,000/QALY and $25,000 to <$35,000/QALY, respectively).

Table 2: Summary of ICERs for CsA-naïve patients

	Parameters changed	ICER/QALY
A	Base case March 2020	$[redacted][1]
B	Phototherapy costs revised to two sessions/week	$[redacted][1]
C	Maintenance of response applied as per March 2020 pre-PBAC response	$[redacted][1]
D	Apply **B** & **C**	$[redacted][2]
E	Apply updated medical resources costs to **D**	$[redacted][2]
F	With proposed price reduction (DPMQ = $[redacted])	$[redacted][1]

The redacted values correspond to the following ranges:
[1]$45,000 to <$55,000/QALY gained
[2]$55,000 to <$65,000/QALY gained

4.6 In March 2020, the PBAC agreed with the ESC that the magnitude of cost offsets from phototherapy applied in the model was not reasonable; particularly as the model included no effectiveness from phototherapy utilisation (paragraphs 6.61 and 7.18, dupilumab Public summary document (PSD) March 2020 PBAC).

4.7 In its proposal, the sponsor maintained that the assumptions informing the number of phototherapy courses per year (courses of phototherapy and weeks per course) based on a clinician survey are valid. The sponsor's proposal claims that while the assumption of three phototherapy session per week is consistent with *Patrizi et al 2015*, it has been changed to two sessions per week in the revised economic model.

4.8 In March 2020, the PBAC considered the ICER to be underestimated due to the submission's assumption regarding maintenance of response, where the maintenance of response was assumed to be higher for dupilumab compared with the comparator in the model. The PBAC noted that there are limited data available to inform these assumptions (paragraph 7.17, dupilumab Public Summary Document March 2020 PBAC).

4.9 The pre-PBAC response for the March 2020 submission provided a respecified base case in which the absolute reduction in response from year 1 to year 2 was

approximately the same for both the dupilumab and standard of care arms (approximately 13%). This approach is used in the sponsor's proposal.

4.10 The sponsor's proposal also updated the unit costs for the medical resource utilisation so that they reflected 2020 costs. This adjustment reduced the ICER from $55,000 to <$65,000/QALY to $55,000 to <$65,000/QALY for CsA-naïve patients (Table 2, ICERs prior to application of revised dupilumab price).

4.11 In March 2020, the PBAC considered the ICER to be underestimated due to the overestimation of the extent of phototherapy use and the assumptions regarding maintenance of response, and that the effective price for dupilumab should be reduced to address the likely underestimation of the ICER (paragraphs 7.16 and 7.17, dupilumab Public Summary Document March 2020 PBAC).

4.12 The new effective price that the sponsor has proposed is approximately 8.3% lower (at ex-manufacturer level) than proposed in the March 2020 submission, resulting in an ICER of $45,000 to <$55,000/QALY (CsA-naive).

Estimated PBS usage & financial implications

4.13 In March 2020, the PBAC noted that the financial estimates would need to be revised to (paragraph 7.18, March 2020 dupilumab PSD):

- Include patients aged 12-17 years. The PBAC noted that a reduced dose (200 mg every other week) is recommended in patients aged 12-17 years with a body weight of <60 kg and considered the reduced dose should be accounted for in the financial estimates.
- Apply the uptake rates of 5% in year 1, increasing to 7.5% in year 6 such that they reflect the proportion of continuing patients in each year rather than only the initiating patients.

4.14 In addition to the above changes, the proportion of patients with uncontrolled AD was revised in the pricing proposal.

4.15 In March 2020, the PBAC considered it would be reasonable to expand the population on which the estimates are based to include the Australian population aged 12-17 years with the remaining assumptions regarding the proportion of patients treated unchanged (paragraph 7.18, dupilumab PSD March 2020 PBAC). The PBAC noted, based on the population data included in the submission, that expanding the population increases the population size by approximately 9%. The PBAC noted that a reduced dose (200 mg every other week) is recommended in patients aged 12-17 years with a body weight of <60 kg. This has been addressed in the sponsor's proposal consistent with the March 2020 PBAC PSD.

4.16 In the March 2020 resubmission the proportion of patients with uncontrolled AD (and therefore considered for treatment with dupilumab) was estimated to be 68%. During the evaluation of the March 2020 resubmission it was stated that it was inappropriate to have assumed some severe AD patients would be 'adequately controlled' on

treatment. It was further noted in the evaluation that this is a major source of uncertainty in the financial estimates and may underestimate the eligible patients (Table 19, Dupilumab PSD, March 2020 PBAC Meeting). The PBAC did not recommend revision of this input. The financial estimates in the pricing proposal assumed 100% of severe patients have uncontrolled AD and hence would be eligible for dupilumab treatment. This change increases the estimated patient numbers substantially (see Table 4 below).

4.17 In March 2020, the PBAC noted that the uptake rates of 5% in year 1, increasing to 7.5% in year 6 were applied to the prevalent pool of eligible patients each year to calculate the number of patients initiating treatment (paragraph 6.56, dupilumab PSD March 2020 PBAC). When continuing patients are taken into account the overall uptake is higher, and by year 6 continuing patients represented 14% of the eligible patients (6,036/44,248). The PBAC considered that it was reasonable that the overall uptake of dupilumab would increase in each year, accounting for both new and continuing patients. However, the PBAC considered it is not reasonable to assume the uptake rate of new patients from the prevalent pool would increase each year. The PBAC considered that the uptake rates of 5.5% in year 2, increasing to 7.5% in year 6 should be applied such that they reflect the proportion of continuing patients in each year (e.g. 3,319 continuing patients in year 6 is 7.5% (3,319/44,248) of the eligible patients).

4.18 The sponsor's proposal stated that the application of uptake rates as per the PBAC's feedback is not intuitive for a first-in-class biologic therapy, nor is it consistent with previous experience reported in DUSC reviews for biologic initiation and continuation of therapy in the first years of launch. Data from DUSC reviews of biological therapies are presented in the pricing proposal for ankylosing spondylitis, psoriasis and Crohn disease (see Figures 2, 3 and 4 of the pricing proposal).

4.19 The sponsor's estimate of the number of patient initiations using the approach specified in the March 2020 PBAC PSD and the revised estimates as per the pricing proposal are summarised in Table 3. These estimates include adolescent patients as per paragraph 4.13 above and revision to the proportion of patients with uncontrolled AD as per paragraph 4.14 above. The estimates in the pricing proposal are stated to be consistent with real world experience of biologic uptake in Australia with the uptake of dupilumab resulting in an initial bolus of patients being treated in the first two years before the number of initiating patients slowly declines before levelling off in years 4 to 6. It is also stated that the proposed estimates avoid a precipitous decrease from year 3 onwards in the PBAC estimates, which is wholly inconsistent with Australian clinical experience with biologic treatment. In March 2020, the PBAC considered it is not reasonable to assume the uptake rate of new patients from the prevalent pool would increase each year. The proposed revised number of patient initiations are consistent with the uptake rate of new patients from the prevalent pool decreasing each year (See Table 1 above).

Table 3: Patient initiations

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
March 2020 PBAC PSD[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Pricing proposal	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]

[a] adjusted for inclusion of adolescent patients, 100% of patients with uncontrolled AD and uptake applied to continuing patients.
The redacted values correspond to the following ranges:
[1]500 to <5,000

4.20 A comparison of the financial estimates based on the recommendations in the PBAC PSD and the pricing proposal is presented in Table 4. These estimates have been calculated using the financial estimates workbook provided with the March 2020 resubmission and do not include the 200 mg dose strength for dupilumab (i.e. all adolescent patients are assumed to be treated with the adult dose). The March 2020 workbook has been used as the workbook provided with the pricing proposal has the patient initiations hardcoded (see paragraph 4.17) and hence it is not possible to easily assess the impact of each change in a stepwise manner using this spreadsheet. The financial estimates have not been independently evaluated. The Secretariat noted that the estimates using the March 2020 workbook are lower than those using the pricing proposal workbook. In its pre-PBAC response, the sponsor clarified that its proposed patient initiation rates should be updated in the March 2020 submission workbook as per the table below:

Table 4: Patient initiation percentages (using March 2020 submission financial estimates model)

Year	2020	2021	2022	2023	2024	2025
Patient initiation (%)[a]	5.0%	4.50%	4.00%	3.50%	3.50%	3.50%

Source: Pre-PBAC Response, Table 1
[a] Input for Row 41 of tab "2a. Patients –epi" in dupilumab March 2020 submission Section 4 model

Table 5: Patient initiations and financial impact

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Recommended approach as per March 20 PBAC minutes							
PBAC minutes March 2020, initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
Add adolescents (9% increase), initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
Revised uptake, % of eligible patients	5.0%	4.2%	2.7%	2.5%	2.6%	2.7%	
Uptake, initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
Scripts	[redacted][2]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][5]
Net PBS/RPBS cost with price in March 20 resubmission (Row A)	$[redacted][11]	$[redacted][12]	$[redacted][12]	$[redacted][13]	$[redacted][13]	$[redacted][14]	$[redacted][15]
Net PBS/RPBS cost including price reduction in proposal (Row B)	**$**[redacted][11]	**$**[redacted][11]	**$**[redacted][12]	**$**[redacted][12]	**$**[redacted][13]	**$**[redacted][13]	**$**[redacted][15]
Pricing proposal							
PBAC minutes March 2020, initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	

Add adolescents (9% increase), initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
100% of patients with uncontrolled AD	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
Revised uptake*	5.0%	4.5%	4.0%	3.5%	3.5%	3.5%	
Uptake, initiating patients	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	
Scripts	[redacted][3]	[redacted][4]	[redacted][6]	[redacted][7]	[redacted][8]	[redacted][9]	[redacted][10]
Net PBS/RPBS cost with price in March 20 resubmission (Row C)	$[redacted][12]	$[redacted][13]	$[redacted][14]	$[redacted][16]	$[redacted][17]	$[redacted][18]	$[redacted][19]
Net PBS/RPBS cost including price reduction in proposal, as presented in pricing proposal (Row D)	**$**[redacted][12]	**$**[redacted][13]	**$**[redacted][14]	**$**[redacted][16]	**$**[redacted][17]	**$**[redacted][20]	**$**[redacted][19]

Source: Compiled during preparation of the minor overview
*Updated based on information provided in Table 1 of pre-PBAC response
Source: Compiled during preparation of the minor overview
*Updated based on information provided in Table 1 of pre-PBAC response
The redacted values correspond to the following ranges:
[1]*500 to <5,000*
[2]*20,000 to <30,000*
[3]*30,000 to <40,000*
[4]*40,000 to <50,000*
[5]*200,000 to <300,000*
[6]*50,000 to <60,000*
[7]*60,000 to <70,000*
[8]*70,000 to <80,000*
[9]*80,000 to <90,000*
[10]*300,000 to <400,000*
[11]*$20 million to <$30 million*
[12]*$30 million to <$40 million*
[13]*$40 million to <$50 million*
[14]*$50 million to <$60 million*
[15]*$200 million to <$300 million*
[16]*$60 million to <$70 million*
[17] *$70 million to <$80 million*
[18]*$90 million to <$100 million*
[19]*$300 million to <$400 million*
[20]*$80 million to <$90 million*

5 PBAC Outcome

5.1 The PBAC provided further advice in regard to its March 2020 recommendation for the listing of dupilumab for the treatment of patients aged 12 years and older with severe atopic dermatitis who are inadequately controlled on topical therapies, and the sponsor's subsequent listing proposal which included modifications to the economic model and the financial estimates model.

5.2 The PBAC considered that the sponsor's amended inputs to the economic model were acceptable overall in addressing the uncertainties previously outlined regarding phototherapy costs and maintenance of response. However, the PBAC maintained that a price reduction would be required to achieve the base case ICERs considered in March 2020: $45,000 to <$55,000/QALY for the CsA-naïve population and $25,000 to

<$35,000/QALY for the CsA-experienced population. The PBAC noted that based on the sponsor's proposal, the ICER was $45,000 to <$55,000/QALY for the CsA-naïve population.

5.3 In relation to the financial estimates, the PBAC noted that the sponsor's proposal resulted in a significant increase to the total cost of dupilumab, and considered that the cost of the listing should be more closely aligned with the estimates based on the PBAC's March 2020 recommended approach (Row B, Table 5).

5.4 The PBAC noted that the inclusion of two phototherapy sessions per week in the economic model was poorly supported, especially in the context of not specifically modelling the outcomes associated with phototherapy. The PBAC recalled that there are limited data to inform the assumptions regarding maintenance of response over time. Overall, the PBAC considered that the modifications the sponsor made to the economic model were still potentially based on optimistic assumptions that favoured dupilumab, however considered them to be acceptable in the context of high clinical need in this therapeutic area, along with a corresponding price reduction to achieve the same base case ICERs reviewed in March 2020.

5.5 The PBAC noted that the financial estimates were updated to include the adolescent (12 to 17 years) population and to remove offsets for phototherapy use. These amendments were considered consistent with the committee's March 2020 advice.

5.6 The PBAC noted the sponsor's revised approach to the uptake rates applied over time to the prevalent pool of eligible patients. While the PBAC noted that this was different to the method PBAC advised in March 2020, the PBAC acknowledged the proposal's claims that the proposed uptake rates were a better estimate of the pattern of uptake. Importantly, the PBAC considered that the uptake rates of patients from the prevalent pool proposed by the sponsor decreased over time and therefore were reasonable.

5.7 The PBAC noted that the proposed estimates changed the assumption regarding patients being adequately controlled on topical corticosteroids (from 68% to 100%) although the PBAC did not specify that this parameter be changed in the outcome of its March 2020 consideration. The PBAC noted that this revision to the financial estimates (in addition to the proposed adjusted uptake rates) was the main driver of the substantial (over 50%) increase to the total cost of dupilumab over the forward estimates compared to that based on assumptions from the March 2020 recommendation ($300 to <$400 million (Row D, Table 5) vs $200 to <$300 million (Row B, Table 5) over six years). Overall, the PBAC considered that the total cost of dupilumab over six years should not exceed the levels described in Row B, Table 5, with allowance for the following adjustments: revised uptake rates as per the sponsor's proposal (see paragraph 5.6); and a reduced effective price.

5.8 The PBAC restated that a Risk Sharing Arrangement would be required consisting of subsidisation caps based on the estimates and [redacted]% rebate for any expenditure exceeding these caps.

5.9 The PBAC reiterated that there was a high clinical need for effective treatments for severe atopic dermatitis and noted the significant disease burden associated with the condition. The PBAC noted the large number of consumer comments received in support of the PBS listing.

5.10 The PBAC maintained its advice from March 2020 that the criteria prescribed by the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met. Specifically, the PBAC found that in the circumstances of its recommendation for dupilumab:

a) The treatment is expected to provide a substantial and clinically relevant improvement in efficacy over SoC;

b) The treatment is expected to address a high and urgent unmet clinical need, however alternative treatments (including cyclosporin) are available and therefore this criterion is not met; and

c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed.

Outcome:
Advised

6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

7 Sponsor's Comment

The sponsor had no comment.