6.02 APREPITANT
oral capsule, 165mg
Emend®, Merck Sharp & Dohme (Australia) Pty Ltd.

1 Purpose of Application

1.1 The submission requested a general schedule and Section 100 (CT), Authority Required (STREAMLINED) listing for aprepitant for the prevention of acute and delayed chemotherapy induced nausea and vomiting (CINV) associated with carboplatin/oxaliplatin based chemotherapy regimens.

2 Requested listing

2.1 The requested restriction is shown below. Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
APREPITANT Capsule, 165mg	1	5	$[redacted] (Section 100 (CT)) $[redacted] (General Schedule)	Emend® MK

Category / Program	Section 100 – Chemotherapy - related benefits (CT) Section 85 – General Schedule (GE)
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Episodicity:	-
Severity:	-
Condition:	Nausea and vomiting
PBS Indication:	Nausea and vomiting
Treatment phase:	-
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Treatment criteria:	-

Clinical criteria:	The condition must be associated with cytotoxic chemotherapy being used to treat malignancy; AND The treatment must be in combination with a 5-hydroxytryptamine receptor ($5HT_3$) antagonist and dexamethasone; AND Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carboplatin; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; oxaliplatin; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.
Population criteria:	-
Prescriber Instructions	No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.
Administrative Advice	*Aprepitant is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.* *No increase in the maximum quantity or number of units may be authorised.* *No increase in the maximum number of repeats may be authorised.*

2.2 The submission did not present any economic analysis to support PBS listing.

3 Background

3.1 Aprepitant was first recommended for registration by the TGA on 5-6 February 2004.

3.2 Aprepitant has not been previously considered by the PBAC for this indication.

4 Clinical place for the proposed therapy

4.1 The submission claimed that CINV can significantly affect a patient's quality of life. The main areas affected by CINV appear to be the ability to complete the activities of everyday living; emotional well-being; social functioning and cognitive functioning. In addition, CINV can result in metabolic imbalances and nutrient depletion, degeneration of self-care and functional ability, and a decline in the patient's performance and mental status. All of these factors may lead to poor compliance with further chemotherapy treatment and ultimately, worse outcomes attributable to posed price needs to be justified.

4.2 The submission claimed that the baseline risk of vomiting or rescue therapy with oxaliplatin/carboplatin in cycle 1 is around 36.3%. The PSCR (p1) argued that the approach taken by the evaluation to estimate baseline risk of CINV associated with oxaliplatin or carboplatin-based therapy substantially understates the clinical need for primary prophylaxis in the treated population.

4.3 The submission also claimed that the probability of experiencing anticipatory emesis in later cycles is greater in patients who experienced emesis in Cycle 1.

4.4 Finally, the submission claimed that clinicians infrequently intervene to optimise CINV prophylaxis regimens. This claim was in contrast to data provided in Section E of the submission.

4.5 The current PBS listing only allows for the use of aprepitant (in combination with a 5-hydroxytryptamine receptor ($5HT_3$) antagonist and dexamethasone) with carboplatin or oxaliplatin containing regimens after the patient experiences CINV.

4.6 The proposed changes to the PBS listing would allow the use of aprepitant (in combination with a $5HT_3$-antagonist and dexamethasone) from the first chemotherapy cycle to prevent CINV.

4.7 As a result all patients treated with carboplatin or oxaliplatin would receive aprepitant in every chemotherapy cycle, rather than a proportion of patients (those experiencing CINV) for some cycles (cycle 2 onwards, depending on when they experience the CINV).

5 Comparator

5.1 The submission nominated standard treatment, comprising of dexamethasone + ondansetron as the comparator. Currently patients treated with oxaliplatin/carboplatin would be eligible to receive aprepitant in cycles 2+ if they experience CINV.

5.2 The PBAC considered that the appropriate comparator would be secondary prophylaxis, i.e. aprepitant after experiencing CINV, as this is the therapy that would most likely be replaced.

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item.

Consumer comments

6.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

6.3 The submission was based on a series of meta-analyses of four head-to-head trials comparing a regimen containing aprepitant or fosaprepitant, to one not containing these drugs.

6.4 Details of the trials presented in the submission are provided in the table below.

Table 1: Trials and associated reports presented in the submission

Trial ID/First Author	Protocol title/ Publication title	Publication citation
Direct randomised trials		
Protocol 031	A Phase III, Randomized, Double-Blind, Active Comparator-Controlled Parallel-Group Study, Conducted Under In-House Blinding Conditions, to Examine the Efficacy and Safety of a Single 150 mg Dose of Intravenous Fosaprepitant Dimeglumine for the Prevention of Chemotherapy-Induced Nausea and Vomiting (CINV) Associated With Moderately Emetogenic Chemotherapy (Protocol 031)	23 June 2015
Nishimura 2015	Nishimura J., Satoh T., Fukunaga M., Takemoto H., Nakata K., Ide Y., Fukuzaki T., Kudo T., Miyake Y., Yasui M., Morita S., Sakai D., Uemura M., Hata T., Takemasa I., Mizushima T., Ohno Y., Yamamoto H., Sekimoto M., Nezu R., Doki Y., Mori M. Combination antiemetic therapy with aprepitant/fosaprepitant in patients with colorectal cancer receiving oxaliplatin-based chemotherapy (SENRI trial): A multicentre, randomised, controlled phase 3 trial. 2015.	*European Journal of Cancer* 2015; 51(10): 1274-1282
Tanioka 2013	Tanioka M., Kitao A., Matsumoto K., Shibata N., Yamaguchi S., Fujiwara K., Minami H., Katakami N., Morita S., Negoro S. A randomised, placebo-controlled, double-blind study of aprepitant in nondrinking women younger than 70 years receiving moderately emetogenic chemotherapy.	*British Joumal of Cancer* 2013; 109(4): 859-865
Rapoport 2010 or Protocol 130 (P130)	A Randomized, Double-Blind, Parallel-Group Study Conducted Under In-House Blinding Conditions to Determine the Efficacy and Tolerability of Aprepitant for the Prevention of Chemotherapy-Induced Nausea and Vomiting Associated With Moderately Emetogenic Chemotherapy. Rapoport B.L., Jordan K., Boice J.A., et al. Aprepitant for the prevention of chemotherapy-induced nausea and vomiting associated with a broad range of moderately emetogenic chemotherapies and tumor types: A randomized, double-blind study.	December 2008. *Supportive Care in Cancer* 2010; 18(4): 423-431

Source: Table B.2-2, p43 of the submission

6.5 The key features of the direct randomised trials are summarised in the table below.

Table 2: Key features of the included evidence

Trial	N	Treatment	Control	Design/ duration	Risk of bias	Patient population	Outcome
Protocol 031	1,000	Day 1: Fosaprepitant 150mg IV + ondansetron 8mg PO BID + dexamethasone 12mg PO Day 2-3: Placebo	Day 1: Placebo IV + ondansetron 8mg PO twice + dexamethasone 20mg PO Day 2-3: Ondansetron 8mg PO BID	R, DB 120 hours	Low	Treated with a range of MECs	Complete response
Nishimura 2015	413	Day 1: Aprepitant 125mg PO / aprepitant *[should be fosaprepitant]* 150mg IV + 5-HT3 receptor antagonist + dexamethasone 6.6mg IV Day 2-3: Aprepitant 80mg PO[a] + dexamethasone 2mg PO BID[b]	Day 1: 5-HT3 receptor antagonist IV + dexamethasone 9.9mg IV Day 2-3: Dexamethasone 4mg PO BID	R, OL 120 hours	High	Treated with FOLFOX, XELOX or SOX	Complete response
Tanioka	91	Day 1: Aprepitant 125mg	Day 1: Granisetron	R, DB	Mod-	Treated with	Complete

Trial	N	Treatment	Control	Design/ duration	Risk of bias	Patient population	Outcome
2013		PO + granisetron 1mg IV + dexamethasone 12mg IV Day 2-3: Aprepitant 80mg PO + dexamethasone 4mg IV	1mg IV + dexamethasone 20mg IV Day 2-3: Dexamethasone 8mg IV	120 hours	erate	carboplatin or irinotecan	response
Rapoport 2010	848	Day 1: Aprepitant 125mg PO + ondansetron 8mg PO BID + dexamethasone 12mg PO Day 2-3: Aprepitant 80mg PO	Day 1: Ondansetron 8mg PO BID + dexamethasone 20mg PO Day 2-3: Ondansetron 8mg PO BID	R, DB 120 hours	High	Treated with a range of MECs, including ACs	Complete response
Meta-analysis	1,352			Included all studies			

AC: anthracycline; BID: twice daily; DB: double blind; FOLFOX: Folonic acid + fluorouracil + oxaliplatin; IV: intravenous; MC: multi-centre; MEC: moderately emetogenic cancer chemotherapy; OL: open label; PO: orally; R: randomised; SOX: S-1 and oxaliplatin; XELOX: capecitabine + oxaliplatin.
Source: compiled during the evaluation

Comparative effectiveness

6.6 **Table 3: Results of complete response (overall phase) across the direct randomised trials**

Trial ID	Aprepitant n with event/N (%)	Control n with event/N (%)	Absolute difference RD (95% CI)	Relative difference OR (95% CI)	*NNT (95% CI)*
Protocol 031	387/502 (77.1)	333/498 (66.9)	0.10 (0.05, 0.16)	1.67 (1.26, 2.21)	*10.0 (6.3, 20.0)*
Nishimura 2015	159/187 (85.0)	136/183 (74.3)	0.11 (0.03, 0.19)	1.96 (1.17, 3.30)	*9.1 (5.3, 33.3,)*
Tanioka 2013	28/45 (62.2)	24/46 (52.2)	0.10 (-0.10, 0.30)	1.51 (0.65, 3.48)	*10.0 (3.3, NA)*
Rapoport 2010	292/425 (68.7)	229/407 (56.3)	0.12 (0.06, 0.19)	1.71 (1.29, 2.27)	*8.3 (5.3, 16.7)*
Pooled result, random effects	*866/1,159 (74.7)*	*722/1,134 (63.7)*	0.11 (0.07, 0.15)	1.71 (1.43, 2.05)	*9.1 (6.7, 14.3)*
Chi-square for heterogeneity: *P=0.94*					

Source: Table B.6-1, p81 of the submission and calculated during evaluation

6.7 The results from the meta-analyses demonstrated that (p79 of the submission):

- A statistically significantly higher proportion of patients treated with aprepitant compared with those receiving the control reported complete response in the overall (0-120 hours following initiation of chemotherapy), acute (0-24 hours following initiation of chemotherapy) and delayed phases (25-120 hours).
- A statistically significantly higher proportion of patients treated with aprepitant compared with those receiving the control reported no vomiting consistently in the overall phase, the acute phase, and the delayed phase.
- A statistically significantly higher proportion of patients treated with aprepitant compared with those treated with the control regimen did not require rescue medication in the overall phase.
- A statistically significantly higher proportion of patients treated with aprepitant compared with those treated with the control regimen reported no significant nausea in the overall phase.
- The time to first vomiting, regardless of use of rescue medication, was

statistically significantly longer in patients treated with aprepitant compared with those receiving the control ($p < 0.001$ in both Protocol 031 and Rapoport 2010[1]).

- The aprepitant regimen reduced the impact chemotherapy has on daily life compared to the control regimen as measured by the proportion of subjects who had "no impact" of CINV assessed using the Functional Living Index – Emesis (FLIE) questionnaire in the overall phase.

6.8 The ESC noted the following reasons why the comparative effectiveness may be over-estimated:

- Patients were treated with chemotherapies other than oxaliplatin and carboplatin. In particular, the magnitude of comparative effectiveness was overestimated due to Rapoport 2010 including patients treated with anthracycline-containing regimens[2].
- The magnitude of comparative effectiveness may also be overestimated due to Nishimura 2015 using an open-label trial design which collected patient-reported outcomes[3].
- Nishimura 2015, Tanioka 2013 and Rapoport 2010 were analysed on a per protocol basis, and consequently there may be incomplete follow-up bias[4].

6.9 The PSCR (p2) argued that "adjusting for small issues of heterogeneity between the included trials does not significantly alter the magnitude of the observed treatment effect…As noted by the evaluation, using the complete response for non-anthracycline based regimens from Rapoport 2010, the pooled odds ratio is only marginally reduced (from 1.71 to 1.65)."

Comparative harms

6.10 **Table 4: Pooled results, random effects, of adverse events across the direct randomised trials**

Trial ID	Aprepitant n with event/N (%)	Control n with event/N (%)	Absolute difference RD (95% CI)	Relative difference OR (95% CI)	NNT (95% CI)
Any adverse event	703/1136 *(61.9%)*	705/1111 *(63.5)*	-0.02 (-0.06, 0.02)	0.93 (0.79, 1.11)	-
Discontinuations due to AE	3/934 *(0.3%)*	4/915 *(0.4%)*	-0.00 (-0.01, 0.00)	0.74 (0.16, 3.38)	-
Serious adverse events	51/1136 *(4.5%)*	55/1108 *(5.0%)*	-0.00 (-0.02, 0.01)	0.84 (0.45, 1.60)	-

Source: Table B.6-10, Figure B.6-8, Table B.6-11, Figure B.6-9, Table B.6-12 and Figure B.6-10, p94-96 of the submission and calculated during the evaluation

6.11 The results from the meta-analyses demonstrated that:

- There were no statistically significant differences between the aprepitant and

[1] Not reported in the other trials.
[2] Using the rates of complete response in the overall phase from the non-anthracycline-containing regimen reduced the odds ratio to 1.65 (95%CI: 1.35, 2.03) (and the risk difference to 0.10 (95%CI: 0.06, 0.14)). Note that the results remain statistically significant.
[3] Exclusion of Nishimura 2015 reduces the pooled odds ratio from 1.71 (95%CI: 1.43, 2.05) to 1.60 (95%CI: 1.28, 2.00), although the results remain statistically significant.
[4] In Nishimura 2015 90.3% and 88.8% of randomised patients in the aprepitant and control group, respectively, were included in the analysis. In Tanioka 2013 95.7% and 97.9% of randomised patients in the aprepitant and control group, respectively, were included in the analysis. In Rapoport 2010 98.8% and 97.4% of randomised patients in the aprepitant and control group, respectively, were included in the analysis.

control regimen with respect to any of the safety outcomes, including proportion of patients experiencing an adverse event or a serious adverse event, and proportion of patients discontinuing treatment prematurely. The safety outcomes consistently favoured aprepitant numerically.

- The types of adverse events reported across the RCTs were similar between treatment groups and were comparable to the types of adverse events observed in subjects with cancer receiving emetogenic chemotherapy.

Benefits/harms

6.12 A summary of the comparative benefits and harms for aprepitant versus standard therapy is presented in the table below.

Table 5: Summary of comparative benefits and harms for aprepitant and control

Trial	Aprepitant n with event/N	Control n with event/N	OR (95% CI)	Event rate/100 patients*		RD (95% CI)
				Aprepitant	Control	
Benefits						
Complete response (overall phase)						
Pooled result, random effects	*866/1,159*	*722/1,134*	1.71 (1.43, 2.05)	*74.7*	*63.7*	0.11 (0.07, 0.15)
Harms						
	Aprepitant n with event/N	**Control n with event/N**	**OR (95% CI)**	**Event rate/100 patients***		**RD (95% CI)**
				Aprepitant	**Control**	
-	-	-	-	-	-	-

* Duration of follow-up = 120 hours

Abbreviations: RD = risk difference; OR = odds ratio

Source: Table B.6-1, p81 of the submission and calculated during evaluation

6.13 On the basis of meta-analysis evidence presented by the submission, for every 100 patients treated with aprepitant in comparison to standard therapy;

- Approximately 11 additional patients would have complete response (no vomiting and no rescue therapy) over 120 hours post chemotherapy.

Clinical claim

6.14 The submission described aprepitant as superior in terms of comparative effectiveness and similar in terms of comparative safety over standard treatment. The ESC considered this claim reasonable.

6.15 The PBAC considered that a claim of superior comparative effectiveness and similar comparative safety may be reasonable, however noted that the magnitude of comparative effectiveness may be overestimated for the reasons outlined in paragraph 6.8.

Economic analysis

6.16 The submission did not provide any economic analysis of aprepitant for the prevention of acute and delayed CINV associated with carboplatin/oxaliplatin based chemotherapy regimens compared with standard therapy. In the absence of the type

of economic evaluation that is consistent with the current PBAC Guidelines, the value for money of aprepitant for the prevention of acute and delayed CINV associated with carboplatin/oxaliplatin based chemotherapy regimens, compared with standard therapy, is unknown.

6.17 The PSCR (p3) argued that although a formal economic evaluation was not provided in the submission, "it can be reasonably expected that the incremental cost-effectiveness of aprepitant is similar to (if not greater than) what was previously considered by the PBAC to represent value for money." The ESC considered that a formal cost-effectiveness analysis should be presented, given that the submission has requested a price increase for aprepitant when used as primary prophylaxis with oxaliplatin or carboplatin compared to the current secondary prophylaxis listing. The requested listing would extend use of aprepitant to a broader group of patients, and in the absence of a significant price reduction, the proposed price needs to be justified.

6.18 The submission re-calculated the PBS-published price for aprepitant, which is a weighted average of:

- The effective price for aprepitant when administered in combination with a highly emetogenic chemotherapy (HEC) for the treatment of malignancy, or cyclophosphamide plus an anthracycline for the treatment of breast cancer: $[redacted] per pack (ex-manufacturer).
- The effective price for aprepitant when administered in combination with a moderately emetogenic chemotherapy (MEC) agent: $[redacted] per pack (ex-manufacturer).

Table 6: Summary of current and proposed pricing for aprepitant

Indication	Aprepitant effective price (ex-man)	Pricing weight	Current PBS price (ex-man)	Updated pricing weight	Updated PBS price (ex-man)	Updated PBS price (DPMQ; S85)
Non-MEC regimens	$[redacted]	67%	$[redacted]	92%	$[redacted]	$[redacted]
MEC-regimens	$[redacted]	33%		8%		

Source: Table D.1-2, p115 of the submission

6.19 The Pre-PBAC Response (p3) proposed that the aprepitant price not be reweighted but is maintained at the current level.

Drug cost/chemotherapy 'journey' with oxaliplatin/carboplatin: $[redacted]/$[redacted]

6.20 The estimate was based on 4.35 cycles and 7.28 cycles per chemotherapy journey with carboplatin and oxaliplatin, 93.7% of chemotherapy cycles where aprepitant is used, assuming that one script of aprepitant is administered per cycle, and a cost per script of $[redacted] (including co-payments).

Estimated PBS usage & financial implications

6.21 This submission was not considered by DUSC.

6.22 The submission presented an epidemiological approach to estimating the use and financial implications based on a 10% sample of PBS prescription data for the time period 2006 to 2014.

Table 7: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5
Estimated extent of use with a change to the PBS listing					
Total chemotherapy journeys	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Proportion of chemotherapy journeys with aprepitant	41.4%	50.2%	53.8%	56.3%	57.2%
Scripts of aprepitant*	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Estimated net cost to PBS/RPBS/MBS					
Net cost to PBS/RPBS (excluding co-payments)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net cost to MBS	-	-	-	-	-
Estimated total net cost					
Net cost to PBS/RPBS/MBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net cost to PBS/RPBS/MBS (as proposed in Pre-PBAC Response)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]

* Based on 4.35 cycles and 7.28 cycles per chemotherapy journey with carboplatin and oxaliplatin, 93.7% of chemotherapy cycles where aprepitant is used, assuming that one script of aprepitant is administered per cycle (Section E Spreadsheet.xls),
Source: Table E.2-5 p124 and Table E.2-10 p128 of the submission, Table 1 p5 of the Pre-PBAC Response

The redacted table above shows the number of scripts for aprepitant is estimated to be 10,000 – 50,000 per year at a net cost to the PBS of less than $10 million per year.

6.23 There is a potential for the net financial implications to be less than the estimate in the submission as uptake may be lower as the baseline risk of vomiting or rescue therapy is lower with oxaliplatin/carboplatin (36.3%) compared to an anthracycline (57.5%).

6.24 The PSCR (p4) presented a reanalysis of the proportion of eligible patients treated with aprepitant.

Table 8: Reanalysis of the proportion of patients currently eligible for aprepitant who receive optimal antiemetic intervention

Row	Estimate	Oxaliplatin	Carboplatin	Combined	Source
A	Total chemotherapy journeys	9,530	3,950	13,480	10% sample of PBS data (provided in Section E of the submission)
B	Aprepitant initiated after 1 chemotherapy cycle	750	260	1,010	
C	Proportion of patients prescribed aprepitant after one chemotherapy cycle	7.9%	6.6%	7.5%	
D	Estimated proportion of patients experiencing CINV following one cycle of chemotherapy	36.3%	36.3%	36.3%	Table C.4.2 of commentary (6.02.COM.38)
E	Proportion of eligible patients treated with aprepitant	21.7%	18.1%	20.6%	C / D

Source: PSCR, Table 1 p.4

For more detail on PBAC's view, see section 7 "PBAC outcome"

7 PBAC Outcome

7.1 The PBAC rejected the request to extend the PBS listing of aprepitant to include prevention of acute and delayed chemotherapy induced nausea and vomiting (CINV) associated with carboplatin and oxaliplatin based chemotherapy regimens. In making its recommendation, the PBAC considered that the cost-effectiveness of aprepitant in the proposed population had not been adequately demonstrated by the submission.

7.2 The submission nominated standard treatment, comprising of dexamethasone plus ondansetron, as the comparator. However, the PBAC considered that the appropriate comparator would be secondary prophylaxis, i.e. aprepitant after experiencing CINV, as this is the therapy that would most likely be replaced.

7.3 The submission proposed that aprepitant plus standard antiemetic therapy is clinically superior to standard therapy alone. The PBAC agreed that this claim may be reasonable, however considered that the magnitude of the benefit was uncertain in the specific subgroup of patients treated with carboplatin and oxaliplatin based chemotherapy regimens.

7.4 The PBAC noted that the submission did not present an economic evaluation of aprepitant for the requested indication. The PBAC considered that in the absence of an economic analysis, the cost-effectiveness of aprepitant in the broader population requested could not be determined.

7.5 The submission claimed that since the PBAC had previously determined aprepitant to be cost-effective for management of CINV associated with cyclophosphamide plus an anthracycline being used to treat breast cancer, aprepitant for the proposed population could be considered at least as cost-effective, as the risk difference for management of CINV in the proposed population is greater than that shown for the cyclophosphamide plus an anthracycline regimen. The PBAC considered that there were several reasons why this claim may not be reasonable, including that the comparator in the previous consideration was placebo, the baseline risk of vomiting or rescue therapy is lower with oxaliplatin and carboplatin based regimens compared to an anthracycline based regimen, and the costs previously considered in the 2006 submission were now outdated.

7.6 The PBAC considered that the requested listing would make aprepitant available to a substantially broader population of patients and the financial implications of such an extension to listing were uncertain. The PBAC considered that if the listing was extended in the future, there should be a risk sharing mechanism to manage for potential use beyond the estimated patient numbers.

7.7 The PBAC considered that a pragmatic way forward would be to cost-minimise the price of aprepitant in the proposed population to the price of aprepitant when used with moderately emetogenic chemotherapy. The PBAC considered that if the sponsor wished to pursue a higher price, a major re-submission with an appropriate economic

evaluation to support a claim of cost-effectiveness would be required.

7.8 The PBAC noted that this submission is eligible for an Independent Review.

Outcome:
Rejected

8 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.

9 Sponsor's Comment

MSD will work with the PBAC to ensure that patients receiving carboplatin and oxaliplatin regimens, which are at the upper end of moderately emetogenic chemotherapy, will be able to access aprepitant on the PBS without first having to have an episode of nausea or vomiting.