6.11 EPLERENONE, Tablet 25 mg, Tablet 50 mg, Inspra® Viatris Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested amendments to the current PBS restriction for eplerenone (Inspra®) to align with clinical guidelines for the management of heart failure. The current PBS restriction restricts subsidy of eplerenone to:

1.2 be prescribed for heart failure with a left ventricular ejection fraction (LVEF) of 40% or less;

1.3 be prescribed when heart failure is diagnosed within 3 to 14 days following an acute myocardial infarction; and

(1) treatment must be commenced within 14 days of an acute myocardial infarction.

1.4 The submission noted that the current Australian and European guidelines for heart failure recommended a mineralocorticoid receptor antagonist (MRA) in all patients with heart failure with reduced ejection fraction (HFrEF) associated with a moderate or severe reduction in LVEF (less than or equal to 40%) unless contraindicated or not tolerated, to decrease mortality and decrease hospitalisation for heart failure. This recommendation was taken from the Guidelines for the prevention, detection and management of heart failure in Australia 2018 and the 2021 European Society of Cardiology (ESC) Guidelines for the diagnosis and treatment of acute and chronic heart failure respectively.

1.5 The submission therefore proposed expansion of the current listing:

1.6 Patient must be symptomatic with NYHA classes II, III or IV, AND

1.7 Patient must have a documented LVEF of less than or equal to 40%, AND

1.8 Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker, AND

(1) Patient must have been stabilised on an angiotensin-converting enzyme (ACE) inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR Patient must have been stabilised on an angiotensin II antagonist at

the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated.

1.9 In 2023, the PBAC Executive recommended that a utilisation review of HF medicines be undertaken, including switching between medicines, combination treatment and add-on therapy. The Executive also advised a literature review of the comparative effectiveness of PBS listed medicines for HF may improve understanding of effectiveness and the place of each medicine in the treatment algorithm. The PBAC considered this utilisation analysis at its September 2024 meeting.

1.10 The utilisation report stated that many patients with HF are older and have a number of chronic conditions (e.g. renal impairment, hypotension) which may result in prescribers choosing a stepwise approach to management (rather than initiation of quadruple therapy as per the Australian Medicines Handbook and the Australian Heart Foundation) and lower maximal doses of medications, to balance benefit with the competing risk of exacerbating other conditions. PBS restrictions for many HF medicines (e.g. ARNI, HCN, eplerenone) predated the evolving treatment paradigm for HF and, in some cases, preclude initiation with quadruple therapy or require a stepwise approach if an adequate clinical response has not been seen. Additionally, current guidelines support quadruple therapy for patients with New York Heart Association (NYHA) Class I HF, whereas PBS restrictions frequently stipulate NYHA Class II or higher (as based on the clinical evidence at the time of listing on the PBS).

1.11 For these reasons, and to be consistent with PBS restrictions, the report considered "standard of care" for HFrEF to be dual therapy with a renin-angiotensin system inhibitor and HF specific beta blocker (BB), with or without an MRA, and with or without a sodium glucose co-transporter 2 inhibitors (SGLT2is) indicated for HF (i.e. dapagliflozin and empagliflozin).

1.12 The submission stated that this analysis/report and the PBAC's consideration of it also formed the rationale for this submission:

- "The PBAC advised it would consider stakeholder input on revising PBS restrictions for HF medicines to align with clinical guidelines in the context of a future PMR. The PBAC was cognisant that the discordance between PBS restrictions and clinical treatment guidelines is likely to reflect clinical scenarios in which HF treatments have not been demonstrated to be cost-effective." (Web Outcomes, September 2024 PBAC Meeting).

2 Background

Registration status

2.1 Eplerenone was TGA registered on 22 June 2005:

- To reduce the risk of cardiovascular death in combination with standard therapy in patients who have evidence of heart failure and left ventricular impairment within 3-14 days of an acute myocardial infarction; and

An extension of the indication for Eplerenone was approved on 30 October 2014:

- To reduce the risk of cardiovascular mortality and morbidity in adult patients with NYHA class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF less than or equal to 30% or LVEF less than or equal to 35% in addition to QRS duration of greater than 130 msec), in addition to standard optimal therapy.

Previous PBAC consideration

2.2 Inspra® was previously considered by the PBAC at its July 2005 meeting. The PBAC recommended listing based on acceptable cost-effectiveness compared with placebo (or standard medical management) where eplerenone treatment is commenced in eligible patients within three to fourteen days of the acute myocardial infarction (eplerenone, Public Summary Document (PSD), July 2005 PBAC meeting).

2.3 No other eplerenone submissions have been considered by the PBAC to date. A major submission was made to the March 2013 PBAC meeting, by Pfizer Pty Limited, seeking to extend the current Authority Required (STREAMLINED) listing to include treatment of New York Heart Association (NYHA) class II (chronic) heart failure with left ventricular systolic dysfunction (LVEF) in addition to standard optimal therapy. (PBAC Web Agenda, March 2013). The submission was not considered by the PBAC, hence no outcomes were published.

3 Requested listing

3.1 The submission requested several amendments to the existing listing.

3.2 The following tables represent the current PBS listing.

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EPLERENONE					
eplerenone 25 mg tablet, 30	8879H	1	30	5	APO-Eplerenone ESPLER Inpler Inspra
eplerenone 50mg tablet, 30	8880J	1	30	5	APO-Eplerenone ESPLER Inpler Inspra
Restriction Summary: 16564 / Treatment of Concept: 4937					
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Treatment Phase: Nil				
	Indication: Heart failure with a left ventricular ejection fraction of 40% or less				
	Clinical criteria:				

	The condition must occur within 3 to 14 days following an acute myocardial infarction,
	AND
	Clinical criteria:
	The treatment must be commenced within 14 days of an acute myocardial infarction
	Caution: Serum electrolytes should be checked regularly
	Prescribing Instructions: The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EPLERENONE					
eplerenone 25 mg tablet, 30	13590G	2	60	5	APO-Eplerenone ESPLER Inpler Inspra
eplerenone 50 mg tablet, 30	13379E	2	60	5	APO-Eplerenone ESPLER Inpler Inspra
Restriction Summary: 16565 / Treatment of Concept: 14266					
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Treatment Phase: Nil				
	Indication: Heart failure with a left ventricular ejection fraction of 40% or less				
	Clinical criteria:				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	Clinical criteria:				
	The condition must occur within 3 to 14 days following an acute myocardial infarction,				
	AND				
	Clinical criteria:				
	The treatment must be commenced within 14 days of an acute myocardial infarction				
	Caution: Serum electrolytes should be checked regularly				
	Prescribing Instructions: The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated				

3.3 The following tables represent the sponsor's proposed listing. Suggested additions from the Secretariat are in italics and deletions are in strikethrough.

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EPLERENONE					

eplerenone 25 mg tablet, 30	8879H	1	30	5	APO-Eplerenone ESPLER Inpler Inspra
eplerenone 50mg tablet, 30	8880J	1	30	5	APO-Eplerenone ESPLER Inpler Inspra

Restriction Summary: 16564 / Treatment of Concept: 4937	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒Authority Required (Streamlined)
	Treatment Phase: Nil
	Indication: Chronic Heart Failure
	Clinical criteria:
	Patient must be both: (i) within 3 to 14 days following an acute myocardial infarction (ii) commenced treatment within 14 days of acute myocardial infarction; OR
	Patient must be symptomatic with NYHA classes II, ~~III or IV~~
	AND
	Clinical criteria:
	Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%
	AND
	Clinical criteria:
	Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker
	AND
	Clinical criteria:
	Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
	Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated
	AND
	Clinical criteria:
	The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist
	Caution: Serum electrolytes should be checked regularly
	Prescribing Instructions: The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
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Restriction Summary: 16565 / Treatment of Concept: 14266	
Concept ID (for internal Dept. use)	**Category / Program:** GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒Authority Required (Streamlined)
	Treatment Phase: Nil
	Indication: Chronic Heart Failure
	Clinical criteria:
	Patient must be both: (i) within 3 to 14 days following an acute myocardial infarction (ii) commenced treatment within 14 days of acute myocardial infarction; OR
	Patient must be symptomatic with NYHA classes II, ~~III or IV~~
	AND
	Clinical criteria:
	Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%
	AND
	Clinical criteria:
	Patient must receive concomitant optimal standard chronic heart failure treatment, which must include a beta-blocker, unless at least one of the following is present in relation to the beta-blocker: (i) a contraindication listed in the Product Information, (ii) an existing/expected intolerance, (iii) local treatment guidelines recommend initiation of this drug product prior to a beta-blocker AND
	AND
	Clinical criteria:
	Patient must have been stabilised on an ACE inhibitor at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR
	Patient must have been stabilised on an angiotensin II antagonist at the time of initiation with this drug, unless such treatment is contraindicated according to the TGA-approved Product Information or cannot be tolerated
	AND
	Clinical criteria:
	The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist
	Caution: Serum electrolytes should be checked regularly
	Prescribing Instructions: The date of the acute myocardial infarction and the date of initiation of treatment with this drug must be documented in the patient's medical records when PBS-subsidised treatment is initiated

3.4 The Secretariat noted that the proposed restriction mirrors the current listing for sacubitril + valsartan (Entresto®). The Secretariat also noted that dapagliflozin was most recently PBS-listed for chronic heart failure (1 March 2024). The pre-PBAC

response agreed that the restriction criteria for dapagliflozin may be a clearer reflection of current clinical practice and may offer a more suitable framework for defining the restriction for eplerenone.

3.5 As discussed in Section 2, the TGA Product Information (PI) states that eplerenone is indicated to reduce the risk of:

- cardiovascular death in combination with standard therapy in patients who have evidence of heart failure and left ventricular impairment within 3–14 days of an acute myocardial infarction (i.e. what is currently listed on PBS); and
- cardiovascular mortality and morbidity in adult patients with NYHA Class II (chronic) heart failure and left ventricular systolic dysfunction (LVEF ≤ 30% or LVEF ≤ 35% in addition to QRS duration of > 130 msec), in addition to standard optimal therapy (i.e. as per the current submission, though the sponsor is proposing NYHA Classes II, III and IV).

3.6 As such, the Secretariat has proposed the following clinical criteria:

Patient must be both: (i) within 3 to 14 days following an acute myocardial infarction (ii) commenced treatment within 14 days of acute myocardial infarction; OR
Patient must be symptomatic with NYHA classes II

The pre-PBAC response proposed removing the reference to NYHA classes or using the following wording: *"Patient must be symptomatic with Heart Failure (NYHA class II or above)".*

3.7 The Secretariat has suggested the inclusion of the following clinical criterion: "The treatment must not be co-administered with an ACE inhibitor or an angiotensin II antagonist". This criterion appears in the current PBS listing for Entresto, but it is also worth noting that the TGA PI for eplerenone states that "the risk of hyperkalaemia may increase when eplerenone is used in combination with an ACE inhibitor and an angiotensin receptor blocker (ARB) and therefore this combination is not recommended".

4 Comparator

4.1 The previous submission considered by the PBAC in July 2005 nominated placebo /standard of care. The nominated comparator remained unchanged in the current submission. The PBAC previously considered the nominated comparator to be appropriate.

4.2 At the time of previous consideration, spironolactone was a restricted benefit for treatment of hyperaldosteronism, including refractory cardiac failure, and female hirsutism (PBS Schedule, April 2005). Spironolactone was subsequently unrestricted from 1 April 2006. As noted in the submission, current Australian guidelines for heart failure recommend an MRA in all patients with HFrEF associated with a moderate or severe reduction in left ventricular ejection fraction (LVEF less than or equal to 40%)

unless contraindicated or not tolerated, to decrease mortality and decrease hospitalisation for heart failure (Atherton et al., 2018).

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from health care professionals (9), individuals who had used this medicine for their own health condition (1), and consumer groups (1) via the Consumer Comments facility on the PBS website. The comments noted that MRA treatment reduces death and hospitalisation outcomes by approximately 30%, and that spironolactone was the preferred MRA due to the current PBS restrictions for eplerenone. The hearts4heart provided input in support of expanding eplerenone's reimbursement criteria, highlighting eplerenone's better tolerability and better efficacy compared to spironolactone.

Clinical trials

5.3 The submission was based on the EPHESUS and EMPHASIS-HF clinical trials. These were large Phase 3, multi-centre, randomised, double-blind, placebo-controlled studies examining the efficacy and safety of Inspra®.

5.4 The EPHESUS trial recruited patients who had a presumptive diagnosis of Acute Myocardial Infarction with Heart Failure (HF), from the onset of the condition to 14 days following the onset. This study formed the basis for the PBAC's decision in June 2005.

5.5 The EMPHASIS-HF study (completed in 2011) recruited patients who had a duration of HF lasting more than 4 weeks, providing evidence for the submission's request to increase the scope of the clinical criteria.

Table 1: Trials presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
PMID: 1266869	Phase 3, multi-centre, randomised, double-blind, placebo-controlled (standard of care) study conducted to investigate the effect of eplerenone as adjunctive treatment to standard therapy on cardiovascular (CV) mortality/morbidity, in patients with HF after an acute myocardial infarction. Pitt B et al; Eplerenone Post-Acute Myocardial Infarction Heart Failure Efficacy and Survival Study Investigators (EPHESUS study).	31 Mar 2003 N Engl J Med. 2003;348(22):2271
NCT00232180	Multicentered, randomized, double-blind, placebo-controlled study conducted to investigate the effects of eplerenone vs. placebo added to fully optimized therapy including an ACE-I (or/and an ARB) and b-blocker in patients with mild (NYHA functional class II) chronic HF with low EF. The primary objective of this trial is to evaluate the efficacy and safety of eplerenone plus standard HF therapy vs. placebo plus standard HF therapy on the cumulative incidence of the composite endpoint of CV death or HF hospitalization, defined as the first occurrence of either HF hospitalization or CV death Zannad Fet al; EMPHASIS-HF Study Group. Eplerenone in patients with systolic heart failure and mild symptoms.	11 Nov 2010 N Engl J Med. 2011 Jan 6;364(1):11-21

Source: Table 2.2, p24 Main Body of the submission.

5.6 The submission did not provide any other evidence in support of the proposed amendments to the current restriction criteria.

Comparative effectiveness

5.7 In the EPHESUS study:

- Kaplan-Meier estimates of mortality at one year were 11.8% in the eplerenone group and 13.6% in the placebo group.
- Reduction in cardiovascular mortality was similar for most common causes, with risk of sudden death being statistically significant (relative risk, 0.79; P=0.03).
- There was a relative reduction of 15 percent in the risk of hospitalization for heart failure with eplerenone (relative risk, 0.85; P=0.03), and there were 23 percent fewer episodes of hospitalization for heart failure in the eplerenone group than in the placebo group (relative risk, 0.77; P=0.002).
- The rate of death from any cause or any hospitalization was 8 percent lower in the eplerenone group than in the placebo group (relative risk, 0.92; P=0.02).

5.8 In the EMPHASIS-HF Trial:

- The hazard ratio for the primary outcome in the eplerenone group, as compared with the placebo group, was 0.63 (95% confidence interval [CI], 0.54 to 0.74; P<0.001).
- A total of 171 patients (12.5%) in the eplerenone group and 213 patients (15.5%) in the placebo group died (hazard ratio, 0.76; 95% CI, 0.62 to 0.93; P = 0.008). In the eplerenone group, 408 patients (29.9%) were hospitalized for any reason, as

compared with 491 (35.8%) patients in the placebo group (hazard ratio, 0.77; 95% CI, 0.67 to 0.88; P<0.001).

- Of the patients receiving eplerenone, 164 (12.0%) were hospitalized for heart failure, as compared with 253 patients (18.4%) receiving placebo (hazard ratio, 0.58; 95% CI, 0.47 to 0.70; P<0.001).
- The total number of hospitalizations (including second and subsequent hospitalizations) was also lower in the eplerenone group (750, vs. 961 in the placebo group, for a 24% reduction; P<0.001), as were the total numbers of hospitalizations for cardiovascular reasons (509 vs. 699, for a 29% reduction; P<0.001) and hospitalizations for heart failure (273 vs. 429, for a 38% reduction; P<0.001).

Comparative harms

5.9 The submission noted that in both studies, patients on eplerenone reported slightly higher potassium levels and higher occurrences of hyperkalaemia.

Clinical claim

5.10 The submission claimed superior comparative effectiveness and inferior comparative safety of eplerenone compared with placebo/standard of care.

5.11 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Economic analysis

5.12 The requested price is based on the current AEMP of eplerenone.

5.13 The submission stated that the price of eplerenone in 2006 (DPMQ $114.84), when it was listed on the PBS, is used to examine the cost effectiveness at the time, and then how that has changed in 2025 (DPMQ $54.09).

5.14 The submission presented an economic analysis where the incremental cost-effectiveness ratio (ICER) was expressed in terms of cost per death avoided or cost per cardiovascular death avoided.

Table 2: Variables used in the base case analysis

Trial	Safety outcome	Eplerenone n (%)	Placebo n (%)	Absolute Risk difference (%)	Events avoided/100 patients annualised
EPHESUS study		3319	3313		
	death from any cause	478 (14.4%)	554 (16.8%)	2.37	2.37
	cardiovascular death	407 (12.3%)	483 (14.6%)	2.36	2.36
EMPHASIS-HF Trial		1364	1373		
	death from any cause	171 (12.5%)	213 (15.5%)	2.98	2.98
	deaths from any cause	147 (10.8%)	185 (13.5%)	2.70	2.70

Source: Table 3.4, p 56 Main Body of the submission

5.15 The submission noted that the cost per death avoided and the cost per cardiovascular death avoided are both lower in the proposed expanded population than the original approved population approved, based on the simple cost per responder analysis.

5.16 As a Category 3 submission, the economic analysis has not been independently evaluated.

Drug cost/patient/year: $649.08

5.17 The estimated drug cost/patient per year would be $649.08 based on a 12-month duration, with treatment ongoing.

5.17.1 The price when eplerenone was listed in 2006 was $114.84 (DPMQ) for one month's treatment. This equates to a 12 monthly cost of $1378.08. This is used as the base case for comparative purposes in this submission. The current DPMQ for eplerenone on the PBS is $54.09, which results in a 12 monthly cost of $649.08.

Estimated PBS usage and financial implications

5.18 The submission used a market share approach to estimate usage and financial implications. The submission did not estimate the size of the population of heart failure patients that is not currently eligible for PBS subsidy and would be if the proposed changes were implemented. The submission instead used the growth rate of Entresto.

5.19 The pre-PBAC response argued against using an epidemiological approach and stated that the market share approach was chosen for the following reasons:

5.20 The requested PBS listing aligned with the current PBS listings of sacubitril/valsartan and should be a reasonable estimate of the patient population as requested for eplerenone.

5.21 Sacubitril/valsartan has the highest number of services and fastest uptake, providing an upper bound for eplerenone. Eplerenone is unlikely to reach this upper bound, as it is already a well-established MRA, and so is unlikely to replicate or exceed Entresto's uptake curve; and

5.22 Spironolactone, the other available MRA on the PBS, is unrestricted and used for multiple indications, preventing a comparison of its isolated use for the HF population.

5.23 The submission estimated that 1,000,000 to < 2,000,000 scripts would be supplied for eplerenone over the first six years of listing (100,000 to < 200,000 in Year 1 to 200,000 to < 300,000 in Year 6).

- The submission stated that the estimated net financial impact to the PBS/RPBS for the proposed listing of eplerenone would be $10 million to < $20 million over six years (Year 1 $0 to < $10 million to Year 6 $0 to < 10 million).

Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications of eplerenone						
Cost to PBS/RPBS less co-payment	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][4]
Estimated financial implications of no change to listing of eplerenone						
Cost to PBS/RPBS less co-payment	$-[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]

[a] Assuming 12 scripts per patient per year as estimated by the submission.
Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Table 1-5 of the Utilisation and Cost Model Workbook of the submission
The redacted values correspond to the following ranges:
[1] *100,000 to < 200,000*
[2] *200,000 to < 300,000*
[3] *$0 to < $10 million*
[4] *$10 million to < $20 million*

6 PBAC Outcome

6.1 The PBAC deferred making a recommendation for the requested amendments to the current PBS restriction for eplerenone (Inspra®) to align with clinical guidelines for the management of heart failure.

6.2 The PBAC noted the lack of mineralocorticoid receptor antagonist (MRA) medication options on the PBS, and the barriers to subsidised access of eplerenone due to the current PBS restriction.

6.3 The PBAC considered that any updated restriction for eplerenone should align with the TGA approved indication.

6.4 The PBAC noted that the submission had nominated placebo/standard of care as the main comparator but considered that spironolactone was a more appropriate comparator as it is the main MRA medication that eplerenone would likely replace in therapy.

6.5 The PBAC noted the significant price difference between spironolactone and eplerenone (i.e. eplerenone being more costly), and considered it was unclear if eplerenone would be cost-effective against spironolactone.

6.6 The PBAC discussed the need for a cost minimisation approach for an expanded population comparing eplerenone to spironolactone, or for eplerenone as a second line therapy to spironolactone to be explored.

6.7 The PBAC considered that an epidemiological approach with assumptions based on relevant clinical advice would be appropriate to estimate the utilisation and financial impact of eplerenone for the new population proposed under the restriction.

6.8 The PBAC considered that further discussions with the sponsor to explore the cost effectiveness of eplerenone with respect to spironolactone and the appropriate approach to present the utilisation and financial estimates would be pragmatic and therefore deferred making a recommendation for the submission at this time.

Outcome:
Deferred

7 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.

8 Sponsor's Comment

Viatris notes the PBAC's continued acknowledgment of subsidised access barriers and limited MRA options for heart failure patients, and looks forward to collaborating on resolving the remaining cost-effectiveness concerns regarding eplerenone.