

## 6.11 EMPAGLIFLOZIN

**Tablet 10 mg,**

**Jardiance<sup>®</sup>,**

**Boehringer Ingelheim Pty Ltd.**

### 1 Purpose of Submission

- 1.1 The Category 4 submission requested to amend the current nurse practitioners (NPs) prescribing arrangements for empagliflozin tablet 10 mg for the treatment of chronic heart failure, from continuing therapy only (CTO) to a shared-care model (SCM).

### 2 Background

- 2.1 Empagliflozin is currently listed on the PBS as an Authority Required (STREAMLINED) listing for chronic heart failure and Type 2 diabetes mellitus.
- 2.2 NPs are currently able to prescribe all PBS listed drugs for the treatment of chronic heart failure, including empagliflozin, as CTO. See Table 1 for a summary of the current PBS listings for chronic heart failure.

**Table 1: Current PBS listings indicated for chronic heart failure**

Drug	Form
dapagliflozin	dapagliflozin 10 mg tablet, 28
ivabradine	ivabradine 5 mg tablet, 56
	ivabradine 7.5 mg tablet, 56
sacubitril + valsartan	sacubitril 24.3 mg + valsartan 25.7 mg tablet, 56
	sacubitril 48.6 mg + valsartan 51.4 mg tablet, 56
	sacubitril 97.2 mg + valsartan 102.8 mg tablet, 56
vericiguat	vericiguat 2.5 mg tablet, 28
	vericiguat 5 mg tablet, 28
	vericiguat 10 mg tablet, 28

Source: Department produced. Correct as of 1 February 2024

### **Registration status**

- 2.3 Empagliflozin was TGA registered on 30 April 2014 for the treatment of Type 2 diabetes mellitus and heart failure.

### **Previous PBAC consideration**

- 2.4 At its November 2021 meeting, the PBAC recommended the listing of empagliflozin tablet 10 mg for the treatment of patients with chronic heart failure. The PBAC advised that empagliflozin for chronic heart failure is suitable for prescribing by NPs for CTO (empagliflozin Public Summary Document (PSD), November 2021 PBAC Meeting). The PSD does not elaborate on why NPs were not considered suitable for initiating treatment with empagliflozin for chronic heart failure. At the time of its consideration,

NPs could only prescribe sacubitril with valsartan for chronic heart failure, and only prescribe empagliflozin for type-2 diabetes mellitus.

2.5 At an Out-of-Session (OOS) meeting between its November 2022 and March 2023 meetings, the PBAC recommended extending the existing listing of empagliflozin to include a General Schedule Authority Required (Streamlined) listing for the treatment of chronic heart failure in patients with a left ventricular ejection fraction (LVEF) greater than 40%. The PBAC reiterated that empagliflozin is suitable for prescribing by NPs within collaborative arrangements as CTO. This was consistent with existing arrangements for empagliflozin for LVEF  $\leq 40\%$  (empagliflozin PSD, December 2022 OOS PBAC Meeting).

### **Collaborative arrangements**

2.6 At the time of consideration, the expectation was that NP prescribing under the PBS was restricted by the NP's scope of practice, state and territory prescribing rights, the prescriber being an authorised NP and having collaborative arrangements in place.

2.7 In addition to the collaborative arrangements, certain medicines had additional conditions for prescribing by NPs, as recommended by the PBAC. These include:

- CTO model: where the patient's treatment and prescribing of a medicine has been initiated by a medical practitioner (MP), but a NP continues the prescribing.
- SCM: where care is shared between a NP and MP in a formalised arrangement with an agreed plan to manage the patient, in a patient-centred model of care.

2.8 In 2022, the Department commissioned an independent review of the collaborative arrangements. The review did not find evidence to support the continuation of collaborative arrangements. The Government committed to remove the legislated requirement for collaborative arrangements for NPs and endorsed midwives (EMs) through the 2023-24 Budget. A project has commenced for the removal of these collaborative arrangement requirements from relevant health legislation (e.g., the National Health Act 1953).

### **Committee-In-Confidence information**

2.9 [Redacted]

2.10 [Redacted]

2.11 [Redacted]

2.12 [Redacted]

### **End Committee-In-Confidence information**

### 3 Requested listing

3.1 The submission requested the following changes to the existing listing. Suggested additions are in italics and deletions are in strikethrough.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
EMPAGLIFLOZIN					
empagliflozin 10 mg tablet, 30	12918X	1	30	5	Jardiance
<b>Restriction Summary 12477 / Treatment of Concept: 12477</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> <i>For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.</i>				
	<b>Administrative Advice:</b> <b>Shared Care Model:</b> <i>For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.</i>				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
<b>Indication:</b> Chronic heart failure					
<b>Clinical criteria:</b>					
Patient must be symptomatic with NYHA classes II, III or IV					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%					
<b>AND</b>					
<b>Clinical criteria:</b>					
The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated					
<b>AND</b>					
<b>Clinical criteria:</b>					
The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or					
The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or					

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	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
EMPAGLIFLOZIN					
empagliflozin 10 mg tablet, 30	13695T	1	30	5	Jardiance
<b>Restriction Summary 14527/ Treatment of Concept: 14471</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
	<b>Administrative Advice:</b> <b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.				
<b>Indication:</b> Chronic heart failure					
<b>Clinical criteria:</b>					
Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy)					
<b>AND</b>					
<b>Clinical criteria:</b>					

	Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor

- 3.2 The PBAC has previously noted, in its consideration of other requests for NP prescribing, that its intention was to allow prescribing only by NPs who are trained in managing the listed conditions. However, it considered that no additional restriction criteria would be required for such listings when including NPs as eligible prescribers (paragraph 4.3, methotrexate, Minutes, September 2023 PBAC meeting).

## 4 Consideration of the evidence

### *Sponsor hearing*

- 4.1 There was no hearing for this item.

### *Consumer comments*

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

### *Nurse Practitioner input*

- 4.3 The submission provided input from several cardiology and heart failure NPs in support of the requested amendment. The input stated that limiting nurse practitioner prescribing to continuing treatment results in unnecessary delays to the initiation of guideline directed medical therapy with sodium-glucose cotransporter-2 (SGLT2) inhibitors. The comments mentioned that empagliflozin is recognised in Australian and international heart failure guidelines as one of the foundational treatment pillars to reduce the risk of cardiovascular death and hospitalisations due to heart failure. Early benefits are seen within one to two weeks of treatment initiation.
- 4.4 The input stated that nurse practitioners are highly skilled at assessing patients with chronic heart failure in accordance with local heart failure guidelines. The input asserted that NPs are often more accessible to patients than MPs as they can provide care at both heart failure clinics and in home visits, meaning that patients can be seen earlier by a healthcare professional and be initiated on guideline-directed medical therapy. The input did not provide any comparative evidence or advice to support that NPs are equally suitable to prescribe empagliflozin for the treatment of chronic heart failure in relation to MPs.

***Basis of the request***

- 4.5 The submission recalled recent positive PBAC considerations across multiple therapeutic areas to allow NPs to initiate prescriptions for certain medicines, noting the recommendations made at its March and July 2022 meetings, where it recommended NP prescribing for molnupiravir and erythropoietin stimulating agents (ESAs), respectively. In its July 2022 consideration of the NP prescribing of ESAs, the PBAC noted that the submission considered NP prescribing would increase administration efficiency and improve access for vulnerable populations including patients in remote and regional areas, the elderly, and those who may be disengaged from care (paragraph 2.6, ESA, Minutes, July 2022 PBAC Meeting).
- 4.6 At its September 2023 meeting, the PBAC recommended the current PBS listings of low-dose methotrexate used for the management of rheumatological conditions to include NPs as eligible prescribers. The PBAC noted its intention was for the recommendation to apply to NPs who have undertaken specific training in managing rheumatological conditions and who are approved for prescribing low-dose methotrexate (paragraph 4.3, methotrexate, Minutes, September 2023 PBAC meeting).
- 4.7 The PBAC previously noted and raised concerns that there is no public record or way to identify the scope of practice for individual NPs. This creates difficulties in verifying that the PBS prescribing of such items will be limited only to the relevant specialist NPs. The PBAC reiterated that it is the responsibility of health professionals to ensure they comply with the relevant state and territory legislation when prescribing medicines on the PBS, as well as to ensure that they prescribe within the conditions of their registration with the Australian Health Practitioner Regulation Agency (AHPRA) and the requirements set out by their relevant National Board (paragraph 4.4, methotrexate, Minutes, September 2023 PBAC meeting).
- 4.8 The PBAC previously considered the identification of prescriber specialty type and prescribing approvals for PBS prescribers was a broader issue with PBS items and was not specific to NPs. However, it noted that the inability to identify the specialty of NPs could impact the consideration of the suitability of some items for prescribing by NPs on the PBS and that it would support further consideration of this issue in any broader work on prescriber types on the PBS undertaken by the Department (paragraph 4.5, methotrexate, Minutes, September 2023 PBAC meeting).
- 4.9 The submission noted that nurse practitioners work both independently and collaboratively, often within multidisciplinary health teams, and provide flexible and affordable health services to Australian communities including tertiary hospitals. Nurse practitioners play an important role in supporting patients living in regional and remote communities including Indigenous Australians who are disproportionately affected by chronic disease and experience inequitable access to medical care.

- 4.10 The submission stated that there is no requirement in the Product Information for empagliflozin to be initiated only by a MP for the treatment of chronic heart failure. Empagliflozin does not require any dose titration and is taken once daily orally.

### ***Estimated financial implications***

- 4.11 The submission stated that there would be no incremental cost to the Commonwealth with the proposed change to the prescriber type arrangements.
- 4.12 The submission also stated that there could be savings to the hospital system as patients would not need to visit multiple healthcare professionals to obtain a prescription to initiate treatment.
- 4.13 Empagliflozin is subject to a Risk Sharing Arrangement (RSA) for its chronic heart failure indication. The Secretariat noted that allowing NPs to initiate treatment with empagliflozin for chronic heart failure may slightly increase the treated population due to improved access, however noted that any risk associated with an increase in the population size would be managed by the existing RSA.

## **5 PBAC Outcome**

- 5.1 The PBAC recommended the amendment of the NP prescribing arrangements of empagliflozin for the treatment of chronic heart failure from CTO to a SCM.
- 5.2 The PBAC noted the Government commitment to remove the legislated requirement for collaborative arrangements for NPs and EMs. The PBAC decided not to recommend the removal of collaborative arrangements from empagliflozin for the treatment of chronic heart failure pending the implementation of the Government commitment.
- 5.3 The PBAC noted that allowing NPs to initiate treatment with empagliflozin for chronic heart failure could potentially lead to an increase in the treated population due to improved access. However, it considered that any increase in utilisation would align with the intended population estimates when empagliflozin first listed for these indications. Furthermore, the PBAC noted that risk sharing arrangements are in place which would manage any additional utilisation beyond what was estimated.
- 5.4 The PBAC noted that on 1 March 2024, amendments to the restrictions for empagliflozin and the addition of a new item code for increased maximum dispensed quantities were implemented. The PBAC recommended the restriction changes to the NP prescribing arrangements could flow-on dapagliflozin for chronic heart failure.
- 5.5 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically, the PBAC found that in the circumstances of its recommendation for amendment to the NP prescribing arrangements of empagliflozin for the treatment of chronic heart failure, the amendment is not expected to address a high and urgent unmet clinical need.
- 5.6 The PBAC noted that this submission is not eligible for an Independent Review as it

received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended listing

### 6.1 Amend Nurse Practitioner prescribing arrangements:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
EMPAGLIFLOZIN					
empagliflozin 10 mg tablet, 30	12918X	1	30	5	Jardiance
<b>Restriction Summary 12477 / Treatment of Concept: 12477</b>					
<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
	<b>Administrative Advice:</b> <b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
<b>Indication:</b> Chronic heart failure					
<b>Clinical criteria:</b>					
Patient must be symptomatic with NYHA classes II, III or IV <i>prior to initiating treatment with this drug</i>					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%					
<b>AND</b>					
<b>Clinical criteria:</b>					
The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated					
<b>AND</b>					
<b>Clinical criteria:</b>					

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	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or					
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or					
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated					
	<b>AND</b>					
	<b>Clinical criteria:</b>					
	Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor					
<b>MEDICINAL PRODUCT</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>	
<b>medicinal product pack</b>						
EMPAGLIFLOZIN						
empagliflozin 10 mg tablet, 30	13695T	1	30	5	Jardiance	
<b>Restriction Summary 14527/ Treatment of Concept: 14471</b>						
<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					
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<b>Indication:</b> Chronic heart failure						
<b>Clinical criteria:</b>						
Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug						
<b>AND</b>						
<b>Clinical criteria:</b>						
Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%						
<b>AND</b>						
<b>Clinical criteria:</b>						

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	Patient must have documented evidence of structural changes in the heart on echocardiography that would be expected to cause diastolic dysfunction (e.g. left ventricular hypertrophy)				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must have documented evidence of at least one of the following: (i) diastolic dysfunction with high filling pressure on echocardiography, stress echocardiography or cardiac catheterisation; (ii) hospitalisation for heart failure in the 12 months prior to initiating treatment with this drug; (iii) requirement for intravenous diuretic therapy in the 12 months prior to initiating treatment with this drug; (iv) elevated N-terminal pro brain natriuretic peptide (NT-proBNP) levels in the absence of another cause				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor				
<b>MEDICINAL PRODUCT</b>					
<b>medicinal product pack</b>	<b>PBS item code</b>	<b>Max. qty packs</b>	<b>Max. qty units</b>	<b>No. of Rpts</b>	<b>Available brands</b>
EMPAGLIFLOZIN					
empagliflozin 10 mg tablet, 30	14018T <i>Listed 1/3/24</i>	2	60	5	Jardiance
<b>Restriction Summary 15054/ Treatment of Concept: 15051</b>					
<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Continuing Therapy Only:</b> For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.				
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	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
<b>Indication:</b> Chronic heart failure					
<b>Clinical criteria:</b>					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must be symptomatic with NYHA classes II, III or IV prior to initiating treatment with this drug					
<b>AND</b>					

	<b>Clinical criteria:</b>
	Patient must have a documented left ventricular ejection fraction (LVEF) of greater than 40%
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; or
	The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor

6.2 Flow on changes to the Nurse Practitioner prescribing arrangements for the following items indicated for chronic heart failure:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
DAPAGLIFLOZIN					
dapagliflozin 10 mg tablet, 28	12823X	1	28	5	Forxiga
	14073Q	1	28	5	
	14054Q	2	56	5	

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed***

## 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**

The sponsor had no comment.