

**5.24 GEMCITABINE,  
Solution for injection 1 g (as hydrochloride) in 25 mL,  
Solution for injection 2 g (as hydrochloride) in 50 mL,  
Gemcitabine Sandoz<sup>®</sup>,  
SANDOZ PTY LTD**

**1 Purpose of Submission**

- 1.1 The Category 4 submission requested Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of two new forms of gemcitabine (1 g/25 mL injection and 2 g/50 mL injection), hereafter referred to as Gemcitabine Sandoz.
- 1.2 Listing was requested under the same conditions as the existing gemcitabine listing (1 g/26.3 mL injection and 2 g/52.6 mL injection), hereafter referred to as DBL Gemcitabine.

**2 Background**

- 2.1 Gemcitabine is currently listed on the PBS as a Section 100 (Efficient Funding of Chemotherapy) Unrestricted Benefit listing.
- 2.2 EFC medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024*, which allows substitution of brands with the same chemotherapy drug.

***Registration status***

- 2.3 Gemcitabine Sandoz (previously Gemcitabine Ebewe<sup>®</sup>) was TGA registered on 24 June 2011 for:
  - locally advanced or metastatic non-small cell lung cancer;
  - locally advanced or metastatic adenocarcinoma;
  - 5FU refractory pancreatic cancer;
  - bladder cancer alone, or in combination with cisplatin;
  - in combination with paclitaxel, of patients with unresectable, locally recurrent or metastatic breast cancer who have relapsed following adjuvant/neoadjuvant chemotherapy. Prior chemotherapy should have included an anthracycline unless contraindicated; and
  - in combination with carboplatin, or patients with recurrent epithelial ovarian carcinoma, who have relapsed >six months following platinum-based therapy.

- 2.4 The TGA found Gemcitabine Sandoz (200 mg/5 mL injection, 1 g/25 mL injection and 2 g/50 mL injection) to be bioequivalent to the corresponding strengths of the reference product, gemcitabine (as hydrochloride) powder for injection (Gemzar®).
- 2.5 DBL Gemcitabine (1 g/26.3 mL injection and 2 g/52.6 mL injection) was TGA registered on 28 April 2010. The TGA approved indications for Gemcitabine Sandoz are the same as those for DBL Gemcitabine.

### **Previous PBAC consideration**

- 2.6 Gemcitabine Ebewe (now Gemcitabine Sandoz) (200 mg/5 mL injection, 1 g/25 mL injection and 2 g/50 mL injection) was previously considered by the PBAC at its November 2011 meeting. The PBAC recommended the listing of the three above-mentioned strengths as well as the amendment of the then Authority Required listing to an Unrestricted Benefit listing. The PBAC also recommended the addition of an administrative note regarding equivalence of the different gemcitabine products as well as a caution due to concern over the different concentrations of gemcitabine.

#### **NOTE:**

Pharmaceutical benefits that have the form gemcitabine hydrochloride powder for I.V. infusion 200 mg (base) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine hydrochloride solution concentrate for I.V. infusion 200 mg in 20 mL and 200 mg in 5 mL (base) are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form gemcitabine hydrochloride powder for I.V. infusion 1000 mg (base) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine hydrochloride solution concentrate for I.V. infusion 1000 mg in 100 mL and 1000 mg in 25 mL (base) are equivalent for the purposes of substitution.

Pharmaceutical benefits that have the form gemcitabine hydrochloride powder for I.V. infusion 2000 mg (base) (after reconstitution) and pharmaceutical benefits that have the form gemcitabine hydrochloride solution concentrate for I.V. infusion 2000 mg in 50 mL (base) are equivalent for the purposes of substitution.

#### **CAUTION:**

Pharmaceutical benefits containing gemcitabine may have different concentrations.

- 2.7 The submission stated that Gemcitabine Sandoz was previously 'a'-flagged to Gemzar (as was DBL Gemcitabine), though Gemzar is no longer listed on the PBS.

## **3 Requested listing**

- 3.1 The submission requested the listing of Gemcitabine Sandoz under the same conditions as the existing listing for DBL Gemcitabine. Suggested additions are in italics.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. Amount	№.of Rpts	Available brands
<b>GEMCITABINE</b>				
gemcitabine 1 g/26.3 mL injection, 26.3 mL vial	4439P (Public hospital)	3000 mg	17	DBL Gemcitabine
gemcitabine 2 g/52.6 mL injection, 52.6 mL vial	4439P (Public hospital)	3000 mg	17	
gemcitabine 1 g/26.3 mL injection, 26.3 mL vial	7246J (Private hospital)	3000 mg	17	
gemcitabine 2 g/52.6 mL injection, 52.6 mL vial	7246J (Private hospital)	3000 mg	17	
gemcitabine 1 g/25 mL injection, 25 mL vial	4439P (Public hospital)	3000 mg	17	Gemcitabine Sandoz
gemcitabine 2 g/50 mL injection, 50 mL vial)	4439P (Public hospital)	3000 mg	17	
gemcitabine 1 g/25 mL injection, 25 mL vial	7246J (Private hospital)	3000 mg	17	
gemcitabine 2 g/50 mL injection, 50 mL vial)	7246J (Private hospital)	3000 mg	17	
<b>Benefit Type: Unrestricted</b>				
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Unrestricted benefit			
	<b>Caution:</b> Pharmaceutical benefits containing gemcitabine may have different concentrations.			

- 3.2 The submission requested that Gemcitabine Sandoz be ‘a’-flagged with DBL Gemcitabine (that is, the products should be treated as equivalent to each other for the purposes of substitution).
- 3.3 The *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* allows the substitution of brands with the same chemotherapy drug. This means that any PBS listed brand of gemcitabine is already considered equivalent for the purpose of substitution under this arrangement, irrespective of biosimilarity or bioequivalence.
- 3.4 The PBAC is asked to advise if Gemcitabine Sandoz and DBL Gemcitabine could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution.

## 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.

### Economic analysis

- 4.3 The submission did not present a formal economic analysis.
- 4.4 The submission requested the same approved ex-manufacturer price (AEMP) for Gemcitabine Sandoz as the existing listing for DBL Gemcitabine (as of 1 February 2025, the AEMPs are \$24.31 for 1 g/26.3 mL injection and \$38.74 for 2 g/52.6 mL injection).
- 4.5 The equi-effective doses were estimated as 1 mg Gemcitabine Sandoz is equal to 1 mg DBL Gemcitabine. The submission noted that while the amount of diluent used is different between Gemcitabine Sandoz (25 mL and 50 mL) and DBL Gemcitabine (26.3 mL and 52.6 mL) the total mg per infusion is the same (1000 mg and 2000 mg respectively).

### Estimated PBS usage and financial implications

- 4.6 The submission estimated there to be no financial implications to the PBS/RPBS as Gemcitabine Sandoz is expected to only substitute for DBL Gemcitabine. The total cost per patient would not change.

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of scripts dispensed <sup>a</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>
<b>Estimated financial implications of Gemcitabine Sandoz</b>						
Cost to PBS/RPBS less co-payment	\$█ <sup>2</sup>	\$█ <sup>2</sup>	\$█ <sup>2</sup>	\$█ <sup>2</sup>	\$█ <sup>3</sup>	\$█ <sup>3</sup>
<b>Estimated financial implications of DBL Gemcitabine</b>						
Cost to PBS/RPBS less co-payment	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS	\$0	\$0	\$0	\$0	\$0	\$0

Source: Submission Utilisation Cost Model (UCM) Workbook

<sup>a</sup> Assuming 64,879 total scripts in year 1, as assumed by the submission.

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges:

<sup>1</sup> 60,000 to < 70,000

<sup>2</sup> \$0 to < \$10 million

<sup>3</sup> \$10 million to < \$20 million

<sup>4</sup> net cost saving

## 5 PBAC Outcome

- 5.1 The PBAC recommended Section 100 (Efficient Funding of Chemotherapy Program) Unrestricted Benefit listings of two new forms of gemcitabine (1 g/25 mL injection and 2 g/50 mL injection), hereafter referred to as Gemcitabine Sandoz, under the same conditions and on a cost-minimisation basis to the existing gemcitabine listing (1 g/26.3 mL injection and 2 g/52.6 mL injection), hereafter referred to as DBL Gemcitabine.

- 5.2 The PBAC noted that the TGA found both Gemcitabine Sandoz and DBL Gemcitabine to be bioequivalent to the reference product, gemcitabine (as hydrochloride) powder for injection (Gemzar), which is no longer PBS-listed.
- 5.3 The PBAC advised the equi-effective doses to be 1 mg Gemcitabine Sandoz is equal to 1 mg DBL Gemcitabine.
- 5.4 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that Gemcitabine Sandoz and DBL Gemcitabine should be considered equivalent for the purposes of substitution (an administrative note can be included in the listing to this effect).
- 5.5 The PBAC considered that the estimated nil net financial impact is appropriate as Gemcitabine Sandoz is likely to only substitute for DBL Gemcitabine.
- 5.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Gemcitabine Sandoz is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over DBL Gemcitabine, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.7 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 Add new items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. Amount	No.of Rpts	Available brands
gemcitabine 1 g/25 mL injection, 25 mL vial	4439P (Public hospital)	3000 mg	17	Gemcitabine Sandoz
gemcitabine 2 g/50 mL injection, 50 mL vial	4439P (Public hospital)	3000 mg	17	
gemcitabine 1 g/25 mL injection, 25 mL vial	7246J (Private hospital)	3000 mg	17	
gemcitabine 2 g/50 mL injection, 50 mL vial	7246J (Private hospital)	3000 mg	17	
<b>Benefit Type: Unrestricted</b>				
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Unrestricted benefit			
	<b>Caution:</b> Pharmaceutical benefits containing gemcitabine may have different concentrations.			

	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form gemcitabine solution for injection 1 g (as hydrochloride) in 25 mL and pharmaceutical benefits that have the form gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.
	<b>Administrative Advice:</b> Pharmaceutical benefits that have the form gemcitabine solution for injection 2 g (as hydrochloride) in 50 mL and pharmaceutical benefits that have the form gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

***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.