5.27 PALIPERIDONE, I.M. injection (modified release) 25 mg (as palmitate) in pre-filled syringe, I.M. injection (modified release) 50 mg (as palmitate) in pre-filled syringe, I.M. injection (modified release) 75 mg (as palmitate) in pre-filled syringe, I.M. injection (modified release) 100 mg (as palmitate) in pre-filled syringe, I.M. injection (modified release) 150 mg (as palmitate) in pre-filled syringe, Paljuna Monthly, Juno Pharmaceuticals Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule Authority Required (STREAMLINED) listings for a new generic brand of paliperidone monthly long-acting injection (Paljuna Monthly) in 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg strength pre-filled syringe (PFS) forms, for the maintenance treatment of schizophrenia.

1.2 The submission proposed amending the current PBS listings for the originator brand (Invega Sustenna®) of paliperidone monthly injection by separating the existing treatment phase-agnostic listings into initiation and maintenance dosing phases. The submission stated that Paljuna Monthly is intended exclusively for maintenance dosing and should therefore be PBS-listed only for maintenance treatment.

1.3 Listing was requested on a cost-minimisation basis compared to Invega Sustenna, at an equivalent price per injection for each respective strength.

2 Background

2.1 Paliperidone monthly injections in strengths of 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg are currently PBS-listed as General Schedule Authority Required (STREAMLINED) listings for the treatment of schizophrenia. Invega Sustenna is the only brand currently available on the PBS for monthly administration.

2.2 The submission stated that Australian patents (AU2008340101 and AU2015200801), held by the sponsor of Invega Sustenna, cover specific dosing regimens that include two initiation doses of paliperidone, with 150 mg administered on Day 1 and 100 mg

on Day 8, followed by a maintenance dose of 75 mg once monthly, or a recommended range of 25 mg to 150 mg based on individual patient tolerability and/or efficacy.

2.3 The submission claimed that, if the new generic brand is listed for maintenance treatment by separating the existing treatment phase-agnostic PBS listings into initiation (loading) and maintenance phases, generic brands of paliperidone monthly injection could enter the market as early as February 2026. Otherwise, the earliest market entry would be December 2028, when the patents expire.

Registration status

2.4 Paljuna Monthly was registered by the Therapeutic Goods Administration (TGA) on 28 February 2025 for the acute and maintenance treatment of schizophrenia in adults. Unlike the originator brand, Paljuna Monthly was approved for maintenance dosing only. According to the product information (PI), patients must be initiated with another long-acting antipsychotic injection prior to progressing to maintenance dosing of Paljuna Monthly. The TGA has confirmed bioequivalence between Paljuna Monthly and the originator brand, Invega Sustenna.

Previous PBAC consideration

2.5 A generic brand of paliperidone monthly injection (i.e., Paljuna Monthly) has not previously been considered by the PBAC.

3 Requested listing

3.1 The submission requested amendments to the existing listings of Invega Sustenna to enable the listing of the new generic brand for maintenance treatment only.

Add new items as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PALIPERIDONE					
paliperidone 25 mg modified release injection, 1 syringe	NEW MP NP	1	1	5	Invega Sustenna
paliperidone 50 mg modified release injection, 1 syringe	NEW MP NP	1	1	5	Invega Sustenna
paliperidone 75 mg modified release injection, 1 syringe	NEW MP NP	1	1	5	Invega Sustenna
paliperidone 100 mg modified release injection, 1 syringe	NEW MP NP	1	1	5	Invega Sustenna
paliperidone 150 mg modified release injection, 1 syringe	NEW MP NP	1	1	5	Invega Sustenna
Restriction Summary [new]/ Treatment of Concept: [new]					
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Indication: Schizophrenia				
	Treatment Phase: Initial treatment				

Amend existing listings as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
PALIPERIDONE					
paliperidone 25 mg modified release injection, 1 syringe	5100K	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 50 mg modified release injection, 1 syringe	5102M	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 75 mg modified release injection, 1 syringe	5103N	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 100 mg modified release injection, 1 syringe	5107T	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 150 mg modified release injection, 1 syringe	5109X	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly

Restriction Summary 16004 / Treatment of Concept: 4246	
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners
	Restriction type: ☒Authority Required (Streamlined)
	Indication: Schizophrenia
	Treatment Phase: Continuing treatment
	Clinical criteria:
	Patient must have received this drug as their most recent course of PBS-subsidised treatment under the initial treatment restriction

3.2 The Secretariat noted the following issues regarding the submission's proposed changes to the current listings of Invega Sustenna, which include separating treatment into initial and continuing phases and listing the new generic brand (Paljuna Monthly) only for continuing treatment, with 'a' flagging to Invega Sustenna for this phase:

- Under *Section 101(4AACD) of the National Health Act 1953,* if Paljuna Monthly is considered equivalent to Invega Sustenna at the same strengths for the purposes of substitution (i.e., 'a'-flagged to each other in the Schedule), both brands must be treated as equivalent across all restrictions, regardless of treatment phase. The legislation does not allow for 'a' flagging to be applied selectively to specific restrictions or item codes.
- Introducing new PBS item codes and amending the current listings for Invega Sustenna without a clear clinical rationale may lead to confusion for prescribers and patients.
- According to the PI for Invega Sustenna, two initial doses of 150 mg on Day 1 and 100 mg on Day 8 should be administered prior to commencing maintenance dosing. It would be difficult to justify the use of strengths other than 100 mg and 150 mg for the initial treatment phase.

3.3 The Secretariat noted that the requested listings may be feasible if implemented without 'a' flagging, provided the listings remain as Authority Required (STREAMLINED) listings. In this arrangement, the streamlined authority code on the

prescription would be linked to the specific brand's item code, enabling pharmacists to dispense the appropriate item. This would require prescribers to ensure they select the correct item code when prescribing. However, if the restriction were to be amended to a lower level of authority in the future, pharmacists would need to select an item code at the point of dispensing. This could result in the generic brand being dispensed regardless of the intended treatment phase. Additionally, if a prescriber selects the incorrect item code when issuing a continuing prescription for a specific brand, a new prescription would be required for the patient to access their intended brand.

3.4 The Secretariat further noted that if 'a' flagging is not allowed for different brands of paliperidone monthly injection in the continuing treatment phase, pharmacists would be required to supply the same brand for all remaining repeats, consistent with the brand dispensed on the initial prescription.

4 Comparator

4.1 The submission did not nominate a comparator but requested cost-minimisation against Invega Sustenna.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

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

Clinical trials

5.3 The submission did not provide clinical evidence but noted that the TGA has confirmed Paljuna Monthly, a generic paliperidone (as palmitate) modified-release suspension for injection, is bioequivalent to the originator brand, Invega Sustenna. Therefore, there is no clear pharmacological rationale to support a difference in efficacy between Paljuna Monthly and Invega Sustenna when used in either the initiation or maintenance phases of treatment.

Economic analysis

5.4 The submission presented estimated price reductions for paliperidone monthly injection based on weighted average disclosed prices (WADPs) under the price disclosure arrangements, using the current approved ex-manufacturer prices (AEMPs) of Invega Sustenna over the six-year period from 2026 to 2031. The submission included an economic model intended to demonstrate potential savings to the PBS/RPBS from listing a generic brand of paliperidone monthly injection earlier in 2026, rather than in 2028. However, the model was considered inappropriate, as price

reductions through price disclosure arrangements are not regarded as relevant inputs in the economic or financial evaluation of a generic brand listing and should therefore be excluded from such assessments.

5.5 The sponsor subsequently confirmed, in correspondence dated 23 May 2025, that the submission seeks a cost-minimisation approach to Invega Sustenna, with the equivalent price per injection for each respective strength.

Estimated PBS usage and financial implications

5.6 Refer to Table 1, which presents the estimated extent of use and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.7 The submission estimated a net saving of $50 million to < $60 million to the PBS/RPBS over six years by listing the generic brand of paliperidone monthly injection in February 2026 instead of December 2028 following the expiry of relevant patents, assuming a price reduction through the price disclosure arrangements from April 2028, which may occur up to six months earlier depending on market competition.

5.8 As outlined in paragraph 5.4, price reductions through the price disclosure arrangements are not considered appropriate inputs for the economic or financial evaluation. In subsequent correspondence dated 23 May 2025, the sponsor confirmed that listing the generic brand of paliperidone monthly injection at the same price per injection as each corresponding strength of the originator brand would result in no financial impact to the PBS/RPBS.

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Total number of scripts dispensed[a]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of listing Paljuna Monthly in February 2026						
Cost to PBS/RPBS less co-payment	$[redacted][2]	$[redacted][2]	$[redacted][2]	$[redacted][3]	$[redacted][4]	$[redacted][4]
Estimated financial implications of listing Paljuna Monthly in December 2028						
Cost to PBS/RPBS less co-payment	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]	-$[redacted][2]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][5]	$[redacted][5]	-$[redacted][5]	-$[redacted][5]	-$[redacted][5]	-$[redacted][5]

[a] The total number of scripts dispensed for all strengths listed on the PBS was estimated based on PBS and RPBS items processed from October 2023 to September 2024, assuming a market growth rate of 3.5%.
Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Utilisation and cost-model workbook - 6 Year Analysis - Paliperidone 1 Month
The redacted values correspond to the following ranges:
[1] *100,000 to < 200,000*
[2] *$30 million to < $40 million*
[3] *$20 million to < $30 million*
[4] *$10 million to < $20 million*
[5] *$0 to < $10 million*

6 PBAC Outcome

6.1 The PBAC recommended the General Schedule Authority Required (STREAMLINED) listings for a new generic brand of paliperidone monthly long-acting injection (Paljuna Monthly) in 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg strength pre-filled syringe (PFS) forms, under the same circumstances as the PBS-listed originator brand (Invega Sustenna®), for the treatment of schizophrenia.

6.2 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Paljuna Monthly would be acceptable if it were cost-minimised to Invega Sustenna.

6.3 The PBAC noted that the TGA has confirmed bioequivalence between Paljuna Monthly and the originator brand, Invega Sustenna. The PBAC considered that separating the existing treatment phase-agnostic listings into initiation and maintenance dosing phases had the potential to create confusion and unnecessary administrative burden, which could impact patient access. The PBAC considered, in the context of bioequivalence between the products, that Paljuna Monthly should be listed under the same circumstances as the existing brand.

6.4 The PBAC advised that a new prescribing instruction would be appropriate and was also added to the recommended listing, to remind prescribers that the initiation and maintenance dosing of paliperidone once monthly injection must be consistent with the TGA-approved product information. The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, the equivalent strengths of Paljuna Monthly and Invega Sustenna should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule).

6.5 The PBAC considered that listing Paljuna Monthly would not result in a net cost to the PBS/RPBS, as it is expected to substitute for Invega Sustenna without increasing overall market utilisation.

6.6 The PBAC advised that Paljuna Monthly is suitable for prescribing by medical practitioners and nurse practitioners, consistent with the prescribing arrangements for Invega Sustenna.

6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Paljuna Monthly is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Invega Sustenna, 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.

6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add brand to existing items:

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
PALIPERIDONE					
paliperidone 25 mg modified release injection, 1 syringe	5100K	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 50 mg modified release injection, 1 syringe	5102M	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 75 mg modified release injection, 1 syringe	5103N	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 100 mg modified release injection, 1 syringe	5107T	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
paliperidone 150 mg modified release injection, 1 syringe	5109X	1	1	5	[a]Invega Sustenna [a]Paljuna Monthly
Restriction Summary 16004 / Treatment of Concept: 4246					
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒Medical Practitioners ☒Nurse practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Indication: Schizophrenia				
	Prescribing Instructions: *Initiation and maintenance dosing of paliperidone once monthly injection must be consistent with the TGA-approved Product Information.*				

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.