

**5.08 PIOGLITAZONE,
Tablet 15 mg (as hydrochloride),
Tablet 30 mg (as hydrochloride),
Tablet 45 mg (as hydrochloride),
Actos[®],
Celltrion Healthcare Australia Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 4 submission requested General Schedule Restricted Benefit listings for new 30-pack sizes of pioglitazone (Actos[®]) tablets in 15 mg, 30 mg, and 45 mg strengths for the treatment of type 2 diabetes mellitus (T2DM). Given the change in pack size from the currently PBS-listed 28-pack, the submission proposed maximum quantities of 30 and 60 tablets for 30-day and 60-day maximum dispensed quantity (MDQ) listings, respectively, across all strengths, while retaining the current five repeats.
- 1.2 Listing was requested based on a cost-minimisation approach, with an equivalent price per tablet compared to the existing 28-pack for the corresponding strength.

2 Background

- 2.1 Pioglitazone 15 mg, 30 mg, and 45 mg tablets are currently listed on the PBS as General Schedule Restricted Benefit listings for the treatment of T2DM under both the 30-day and 60-day MDQ listings.
- 2.2 There are currently three other brands of pioglitazone 28-tablet packs listed on the PBS (see Table 1), all of which are considered equivalent ('a'-flagged) to Actos for the purposes of substitution across all strengths.
- 2.3 The submission indicated that the new 30-pack size, across all strengths of Actos will replace the currently PBS-listed 28-pack size, if recommended for listing, as the sponsor anticipated shortages in the 28-pack size for both the 15 mg and 30 mg strengths.

Registration status

- 2.4 Pioglitazone was first registered by the Therapeutic Goods Administration (TGA) on 6 February 2001 for the treatment of T2DM inadequately controlled by diet. The TGA registration was updated in 2007 to include triple therapy with metformin and a sulfonylurea. On 5 February 2025, the Australian Register of Therapeutic Goods (ARTG) for Actos was revised to include the new 30-pack size, without any changes to the registered indications.

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2.5 Actos 15 mg, 30 mg, and 45 mg tablets are TGA approved for use with the following recommended doses:

- monotherapy: 15 mg or 30 mg once daily, increasing to 45 mg once daily after four weeks if a greater therapeutic effect is needed.
- dual therapy: 30 mg once daily in combination with sulfonylureas, insulin, or metformin.
- triple therapy: 30 mg once daily in combination with sulfonylurea and metformin. If a greater therapeutic effect is needed, the dose may be increased to a maximum of 45 mg once daily.

Previous PBAC consideration

2.6 The new 30-pack size of Actos has not been considered by the PBAC previously.

3 Requested listing

3.1 The submission requested the following new listings for the 30-pack size of pioglitazone.

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 15 mg tablet, 28	8694N MP NP	1	28	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 15 mg tablet, 30	NEW MP NP	1	30	5	Actos
Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Diabetes mellitus type 2					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 30 mg tablet, 28	8695P MP NP	1	28	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 30 mg tablet, 30	NEW MP NP	1	30	5	Actos
Restriction Summary [new] / Treatment of Concept: [new]					

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<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 45 mg tablet, 28	8696Q MP NP	1	28	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 45 mg tablet, 30	NEW MP NP	1	30	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Diabetes mellitus type 2					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 15 mg tablet, 28	13898L MP NP 60DD	2	56	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 15 mg tablet, 30	NEW MP NP	2	60	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Diabetes mellitus type 2					
Clinical criteria:					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 30 mg tablet, 28	13921Q MP NP 60DD	2	56	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 30 mg tablet, 30	NEW MP NP	2	60	5	Actos

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Restriction Summary [new] / Treatment of Concept: [new]
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2
Clinical criteria:
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 45 mg tablet, 28	14057W MP NP 60DD	2	56	5	APOTEX-Pioglitazone ARX-PIOGLITAZONE Actos Vexazone
pioglitazone 45 mg tablet, 30	NEW MP NP	2	60	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2
Clinical criteria:
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient

- 3.2 The submission requested the listing of the new 30-pack Actos under the same restrictions as the currently PBS-listed 28-pack pioglitazone tablets across all strengths. However, due to the larger pack size, the submission also requested an increase in the maximum quantities to 30 and 60 tablets for 30-day and 60-day MDQ listings, respectively.
- 3.3 The submission did not request that the 30-pack Actos be considered equivalent to the currently PBS-listed 28-pack pioglitazone tablets of the same strengths for the purposes of substitution (i.e., ‘a’-flagged to each other in the Schedule). The PBAC recalled it had previously advised that the new pack sizes of rivaroxaban (Xarelto®) tablets should not be considered equivalent for the purposes of substitution with any brands of any existing pack sizes, noting that allowing substitution between pack sizes may result in increased fees to Government through broken pack fees (paragraph 6.9, rivaroxaban Public Summary Document (PSD), November 2024 PBAC meeting).
- 3.4 The PBAC considered that it would not be appropriate for the 30-pack Actos to be considered equivalent to the currently PBS-listed 28-pack pioglitazone tablets of the same strengths for the purposes of substitution (i.e., ‘a’-flagged in the Schedule), due to the potential increase in government expenditure through broken pack fees.

4 Comparator

- 4.1 The submission nominated the currently PBS-listed 28-tablet packs of Actos as the main comparator. This was appropriate.

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.

Rationale for requested listing

- 5.3 The submission noted that on 25 October 2024, the sponsor lodged a Minimum Stockholding Requirement Breach Notification to the PBS for Actos 15 mg and 30 mg tablets. The submission indicated that the current and anticipated shortages are due to limited supplies from the previous manufacturer and the relocation of manufacturing to a new site, resulting in the change to pack size from 28 to 30 tablets.
- 5.4 The evaluation provided a summary of the currently PBS-listed brands of pioglitazone and their shortage status as of 14 April 2025 in Table 1.

Table 1: Summary of the currently PBS-listed brands of pioglitazone and shortage status

Brand name	Strength	PBS item code	Shortage status/Product availability	Supply impact dates
Actos	15 mg tablets	13898L, 8694N	Anticipated/ Available	01 Jul 2025 to 31 Dec 2025
	30 mg tablets	13921Q, 8695P	Current/ Unavailable	01 Mar 2025 to 31 Dec 2025
	45 mg tablets	14057W, 8696Q		N/A
Vexazone	15 mg tablets	13898L, 8694N	Current/ Limited Availability	05 Mar 2025 to 30 Jun 2025
	30 mg tablets	13921Q, 8695P	Current/ Limited Availability	05 Mar 2025 to 30 Jun 2025
	45 mg tablets	14057W, 8696Q	Current/ Limited Availability	05 Mar 2025 to 30 Jun 2025
ARX-PIOGLITAZONE	15 mg tablets	13898L, 8694N		N/A
	30 mg tablets	13921Q, 8695P		
	45 mg tablets	14057W, 8696Q		
APOTEX-Pioglitazone	15 mg tablets	13898L, 8694N		N/A
	30 mg tablets	13921Q, 8695P		
	45 mg tablets	14057W, 8696Q		

Source: compiled by the Secretariat during evaluation based on [the TGA Medicine shortage reports database](#) accessed on 14 April 2025
Abbreviation: N/A = not applicable

Economic analysis

- 5.5 The submission presented a cost-minimisation analysis for the new 30-pack Actos compared to the currently PBS-listed 28-pack size of the same strengths, based on an equivalent price per tablet.

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5.6 Table 2 provides a comparison of the price of pioglitazone between the different pack sizes across all strengths.

Table 2: Cost-minimisation analysis

Strength (MDQ)	30-day MDQ listing			60-day MDQ listing		
	15 mg (30)	30 mg (30)	45 mg (30)	15 mg (60)	30 mg (60)	45 mg (60)
Current AEMP (28 tablets)	\$6.18	\$9.51	\$12.37	\$6.18	\$9.51	\$12.37
Current AEMP per tablet	\$0.22	\$0.34	\$0.44	\$0.22	\$0.34	\$0.44
Proposed AEMP ^a (30 tablets)	\$6.62	\$10.19	\$13.25	\$6.62	\$10.19	\$13.25
Current DPMQ (28 tablets)	\$20.10	\$23.69	\$26.76	\$26.75	\$33.93	\$40.07
Proposed DPMQ ^b (30 tablets)	\$20.58	\$24.42	\$27.71	\$27.70	\$35.37	\$41.96

Source: Table 3-1 of the submission

Abbreviations: AEMP = approved ex-manufacturer price; DPMQ = Dispensed price maximum quantity; MDQ = maximum dispensed quantities;

^a As of February 2025, the AEMP for the existing 28-pack pioglitazone tablets was \$6.18 for 15 mg, \$9.51 for 30 mg, and \$12.37 for 45 mg. The proposed AEMP for the 30-pack Actos was calculated by dividing each AEMP for the 28-pack size by 28 and then multiplying by 30 for each strength.

^b DPMQ = AEMP x 1.0752 (wholesale mark-up) + \$4.79 (AHI fee) + \$8.67 (Dispensing fee).

Drug cost/patient/year

5.7 The estimated drug cost/patient per year is provided in Table 3.

Table 3: Drug cost/patient/year

Strength (MDQ)	30-day MDQ listing			60-day MDQ listing		
	15 mg (30)	30 mg (30)	45 mg (30)	15 mg (60)	30 mg (60)	45 mg (60)
DPMQ	\$20.58	\$24.42	\$27.71	\$27.70	\$35.37	\$41.96
Script per year	12.17	12.17	12.17	6.08	6.08	6.08
Drug cost/patient/year	\$250.46	\$297.19	\$337.23	\$168.42	\$215.05	\$255.12

Source: Compiled by the Secretariat during evaluation, based on the proposed DPMQ and script equivalence per year for the 30-day and 60-day MDQ listings, which are 12.17 and 6.08, respectively.

Abbreviations: DPMQ = Dispensed price maximum quantity; MDQ = maximum dispensed quantities;

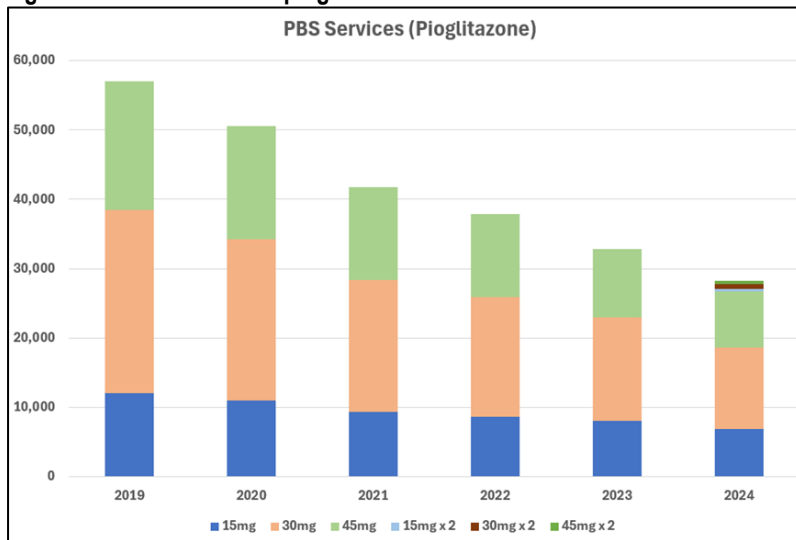
Estimated PBS usage and financial implications

5.8 A market share approach was used to estimate the utilisation and financial impact of listing the new 30-pack pioglitazone tablets.

5.9 Table 4 presents the estimated extent of use, cost to the PBS/RPBS and the net financial implications of listing the 30-pack size to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.10 The submission extrapolated the market growth of pioglitazone based on the number of PBS and RPBS items processed from January 2019 to December 2024 (see Figure 1). The submission noted that the average annual rate of growth observed since 2016 has been a decline of 13.1% and assumed this trend would continue for the next six years.

Figure 1: PBS services for pioglitazone



Source: Figure 4-1 of the submission

- 5.11 The submission assumed that the new 30-pack Actos would substitute for the existing 28-pack sizes of other pioglitazone brands at a script ratio of 13.04:12.17 and considered that the listing of the 30-pack size is not expected to increase the market growth for pioglitazone.
- 5.12 The submission estimated a net cost saving to the PBS/RPBS over the first six years of listing. This is summarised in Table 4. The submission claimed that the proposed listing of the 30-pack would result in a small net saving to the Government, as the savings in supply chain costs (i.e., wholesaler and pharmacy fees) would be greater than the reduction in patient co-payments due to fewer scripts required with the larger pack size.

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Table 4: 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 for pioglitazone:	█ ¹	█ ¹	█ ¹	█ ²	█ ²	█ ²
Number of scripts dispensed substituted by 30-pack	█ ³	█ ²	█ ²	█ ²	█ ³	█ ³
Number of scripts dispensed for 30-pack	█ ³	█ ³	█ ²	█ ²	█ ³	█ ³
Estimated financial implications of 28-pack pioglitazone tablets						
Cost to PBS/RPBS less co-payment	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴
Estimated financial implications of 30-pack Actos						
Cost to PBS/RPBS less co-payment	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵	\$█ ⁵
Net financial implications						
Net cost to PBS/RPBS	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴	-\$█ ⁴

Source: Utilisation and cost model workbook

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

The redacted values correspond to the following ranges:

¹ 20,000 to < 30,000

² 10,000 to < 20,000

³ 5,000 to < 10,000

⁴ net cost saving

⁵ \$0 to < \$10 million

6 PBAC Outcome

- 6.1 The PBAC recommended General Schedule Restricted Benefit listings of pioglitazone 15 mg, 30 mg, and 45 mg 30-pack tablets for the treatment of type 2 diabetes mellitus (T2DM).
- 6.2 Due to the new (larger) 30-pack across all strengths, the PBAC considered that the requested maximum quantities of 30 and 60 tablets would be appropriate for 30-day and 60-day maximum dispensed quantity (MDQ) listings, respectively.
- 6.3 The PBAC noted the current and anticipated shortages of pioglitazone, particularly the 30 mg strength, and that the new 30-pack of the Actos brand will replace the currently PBS-listed 28-pack size, which would help address the supply shortage of pioglitazone.
- 6.4 The PBAC noted that, should the 30-pack pioglitazone tablets be considered equivalent to the currently PBS-listed 28-pack pioglitazone tablets of the same strengths for the purposes of substitution (i.e., ‘a’-flagged to each other in the Schedule), there would be a potential increase in government expenditure through broken pack fees.
- 6.5 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that the new 30-pack pioglitazone tablets should not be considered equivalent to the 28-pack tablets of the same strengths for the purposes of substitution (i.e., not ‘a’-flagged to each other in the Schedule).

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- 6.6 The PBAC advised that the cost-minimisation approach, based on an equivalent price per tablet, was appropriate.
- 6.7 The PBAC noted the estimated net cost saving to the PBS/RPBS over the first six years of listing the 30-pack, primarily due to savings in supply chain costs (i.e., wholesaler and pharmacy fees) being greater than the reduction in patient co-payments from fewer scripts required with the larger pack size.
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the new forms of pioglitazone are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed forms of pioglitazone 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.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items as follows:

30-Day dispensing listings:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 15 mg tablet, 30	NEW MP NP	1	30	5	Actos
Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Diabetes mellitus type 2					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 30 mg tablet, 30	NEW MP NP	1	30	5	Actos
Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					

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Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 45 mg tablet, 30	NEW MP NP	1	30	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2

60 day-dispensing listings:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 15 mg tablet, 30	NEW MP NP 60DD	2	60	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2
Clinical criteria:
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 30 mg tablet, 30	NEW MP NP 60DD	2	60	5	Actos

Restriction Summary [new] / Treatment of Concept: [new]
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
Restriction type: <input checked="" type="checkbox"/> Restricted benefit
Indication: Diabetes mellitus type 2
Clinical criteria:
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
PIOGLITAZONE					
pioglitazone 45 mg tablet, 30	NEW MP NP 60DD	2	60	5	Actos
Restriction Summary [new] / Treatment of Concept: [new]					
<input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
Restriction type: <input checked="" type="checkbox"/> Restricted benefit					
Indication: Diabetes mellitus type 2					
Clinical criteria:					
The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient					

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

8 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.

9 Sponsor's Comment

The sponsor had no comment.