



National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021

No. 139, 2021

**An Act to amend the *National Health Act 1953*, and
for other purposes**

Note: An electronic version of this Act is available on the Federal Register of Legislation
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Contents

1	Short title.....	1
2	Commencement.....	2
3	Schedules.....	2
Schedule 1—Amendments		3
Part 1—Amendments commencing on the day after Royal Assent		3
<i>National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018</i>		3
Part 2—Amendments commencing on 1 July 2022		4
<i>National Health Act 1953</i>		4
Part 3—Amendments commencing on 1 October 2022		36
<i>National Health Act 1953</i>		36
Part 4—Amendments commencing on 1 July 2023		41
<i>National Health Act 1953</i>		41
Part 5—Amendments commencing on 1 July 2027		47
<i>National Health Act 1953</i>		47



National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021

No. 139, 2021

An Act to amend the *National Health Act 1953*, and for other purposes

[Assented to 13 December 2021]

The Parliament of Australia enacts:

1 Short title

This Act is the *National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021*.

No. 139, 2021

National Health Amendment (Enhancing the Pharmaceutical Benefits Scheme) Act 2021

1

2 Commencement

- (1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	13 December 2021
2. Schedule 1, Part 1	The day after this Act receives the Royal Assent.	14 December 2021
3. Schedule 1, Part 2	1 July 2022.	1 July 2022
4. Schedule 1, Part 3	1 October 2022.	1 October 2022
5. Schedule 1, Part 4	1 July 2023.	1 July 2023
6. Schedule 1, Part 5	1 July 2027.	1 July 2027

Note: This table relates only to the provisions of this Act as originally enacted. It will not be amended to deal with any later amendments of this Act.

- (2) Any information in column 3 of the table is not part of this Act. Information may be inserted in this column, or information in it may be edited, in any published version of this Act.

3 Schedules

Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.

Schedule 1—Amendments

Part 1—Amendments commencing on the day after Royal Assent

National Health Amendment (Pharmaceutical Benefits— Budget and Other Measures) Act 2018

1 Part 2 of Schedule 1

Repeal the Part.

2 Part 2 of Schedule 2

Repeal the Part.

3 Part 2 of Schedule 3

Repeal the Part.

3A Part 2 of Schedule 4

Repeal the Part.

Part 2—Amendments commencing on 1 July 2022

National Health Act 1953

4 Subsection 84(1) (at the end of the definition of *approved ex-manufacturer price*)

Add:

Note: See also section 85BA (effect of deemed reductions of, or increases to, the approved ex-manufacturer price).

5 After section 85B

Insert:

85BA Effect of deemed reductions of, or increases to, approved ex-manufacturer price

- (1) If, under a provision of this Part, the approved ex-manufacturer price of a brand of a pharmaceutical item is, or is taken to be, reduced by an amount (the *reduction amount*) or a percentage (the *reduction percentage*):
 - (a) in a case where a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be reduced by the reduction amount or the reduction percentage, as the case requires; or
 - (b) in a case where a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be reduced by the reduction amount or the reduction percentage, as the case requires.
- (2) If, under a provision of this Part, the approved ex-manufacturer price of a brand of a pharmaceutical item is, or is taken to be,

increased by an amount (the *increase amount*) or a percentage (the *increase percentage*):

- (a) in a case where a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be increased by the increase amount or the increase percentage, as the case requires; or
- (b) in a case where a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price of the brand of the pharmaceutical item is taken to be increased by the increase amount or the increase percentage, as the case requires.

6 Section 99AC (paragraph beginning “Subdivision B”)

Repeal the paragraph, substitute:

Subdivision B requires there to be a price reduction for the first new brand of a pharmaceutical item (other than a combination item) when the brand lists. The listing of the new brand of the pharmaceutical item also provides an automatic trigger for price reductions to occur under Subdivision E (see sections 99ACQ and 99ACR).

7 Section 99AC (paragraph beginning “Subdivision C”)

Repeal the paragraph, substitute:

Subdivision C requires there to be a price reduction for the first new brand of a pharmaceutical item that is a combination item when the brand lists. The listing of the new brand of the pharmaceutical item also provides an automatic trigger for price reductions to occur under Subdivision E (see sections 99ACQ and 99ACR).

8 Section 99AC (paragraph beginning “Subdivision D”)

Repeal the paragraph, substitute:

Subdivision D provides for other price reductions for pharmaceutical items. These price reductions include reductions that occur on a certain anniversary of the drug in the pharmaceutical item being a listed drug.

Subdivision E provides for price reductions that are automatically triggered when Subdivision B or C applies to require a first new brand price reduction for a brand of a pharmaceutical item.

9 At the end of section 99ACA

Add:

- (4) A reference in this Division to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACF(2) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.

10 Subdivision B of Division 3A of Part VII (heading)

Omit “25% price reductions for new”, substitute “First new brand price reductions for”.

11 Section 99ACB (heading)

Omit “25% price reduction for new”, substitute “First new brand price reductions for”.

12 Paragraph 99ACB(2)(d)

Omit “40%”, substitute “60%”.

13 After subsection 99ACB(2)

Insert:

- (2A) If the approved ex-manufacturer price mentioned in subparagraph (2)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned

in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

14 Subparagraph 99ACB(3)(a)(i)

Repeal the subparagraph, substitute:

- (i) subsection (5) or (5A);
- (ia) a determination under paragraph (6A)(b);
- (ib) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1);

15 Subparagraph 99ACB(3)(a)(ii)

Before “section 99ACH”, insert “repealed”.

16 Subparagraph 99ACB(3)(a)(iii)

Before “subsection”, insert “repealed”.

17 At the end of paragraph 99ACB(3)(a)

Add:

- (iv) section 99ACQ;
- (v) subsection 99ACR(3) or (4);

18 Subsection 99ACB(3) (note)

Omit “subsection (1) is”, substitute “subsections (5) and (5A) of this section are”.

19 Subsection 99ACB(3) (note)

After “99AEI”, insert “ and subsection (6B) of this section”.

20 Subsection 99ACB(4) (heading)

Omit “25%”, substitute “*First new brand*”.

21 Paragraphs 99ACB(4A)(c) and (d)

Omit “15%”, substitute “35%”.

22 Paragraph 99ACB(4A)(d)

Omit “40%”, substitute “60%”.

23 Subsection 99ACB(4A) (note)

Omit “40%”, substitute “60%”.

24 After subsection 99ACB(4A)

Insert:

- (4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

25 Subsection 99ACB(5A)

Omit “(6B)”, substitute “(6A)”.

26 Paragraphs 99ACB(5A)(a) and (b)

Omit “60%”, substitute “40%”.

27 After subsection 99ACB(5A)

Insert:

- (5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

28 Subsections 99ACB(6A) and (6B)

Repeal the subsections, substitute:

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (6A) The Minister may, by notifiable instrument, determine that:
- (a) the agreed price of the new brand of the trigger item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or
 - (b) the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.
- (6B) If the Minister makes a determination under paragraph (6A)(a), subsections (5) and (5A) are taken not to have applied to the trigger item.

29 Subsection 99ACB(6C)

Omit “or (6B)”.

30 Subsection 99ACB(6D)

Repeal the subsection.

31 Paragraph 99ACC(1)(c)

Omit “an agreed price (the *existing agreed price*) is in force”, substitute “there is an approved ex-manufacturer price”.

32 Paragraph 99ACC(1)(d)

Omit “after the day on which the existing agreed price came into force for the single brand of the combination item:”, substitute “any of the following apply:”.

33 Subsections 99ACC(2) to (5)

Repeal the subsections, substitute:

Price reduction

- (2) Subject to subsections (5A), (5C) and (5E), on the reduction day, the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.
- (3) Different methods may be prescribed by the regulations for different classes of combination items.
- (4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.
- (5) Subject to subsections (5A) and (5C), if the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the single brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the single brand of the combination item is reduced under subsection (2).

Reduction cap

- (5A) If:
 - (a) the approved ex-manufacturer price of the single brand of the combination item is to be reduced under subsection (2); and
 - (b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:
 - (i) 40% of the approved ex-manufacturer price of a listed brand of the combination item on 1 January 2016; or
 - (ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the combination item;the approved ex-manufacturer price of the single brand of the combination item is taken to be reduced under subsection (2) to an amount equal to the capped price.
 - (5B) If the approved ex-manufacturer price mentioned in subparagraph (5A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the
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approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (5C) In relation to the single brand of the combination item, the Minister may, by notifiable instrument, determine that:
- (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.
- (5D) In making a determination under subsection (5C):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the single brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account:
 - (i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and
 - (ii) any other matter the Minister thinks is relevant.
- (5E) If the Minister makes a determination under subsection (5C), the approved ex-manufacturer price of the single brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (5C).

Section does not limit Minister's powers

- (5F) This section does not limit the Minister's powers, on or after the reduction day, to make:
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- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the single brand of the combination item.

34 Paragraph 99ACC(6)(a)

Omit “or 99ADH, or subsection 99ACF(1), (2), (2AB) or (2AC) because of section 99ACH,”, substitute “or 99ACQ or subsection 99ACR(3) or (4) or section 99ADH”.

35 Paragraph 99ACC(6)(c)

Omit “item 2, 3, 4, 5 or 6”, substitute “an item”.

36 Section 99ACD (heading)

Omit “25% price reduction for new”, substitute “**First new brand price reductions for**”.

37 Paragraph 99ACD(1A)(d)

Omit “40%”, substitute “60%”.

38 After subsection 99ACD(1A)

Insert:

- (1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(d)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

39 Subsection 99ACD(2)

Omit “subsection (1) or section 99ACE”, substitute “a listed provision (see subsection (2A))”.

40 Subsection 99ACD(2) (note)

Omit “subsection (1) is”, substitute “subsections (5) and (5A) of this section are”.

41 Subsection 99ACD(2) (note)

After “99AEI”, insert “ and subsection (7B) of this section”.

42 After subsection 99ACD(2)

Insert:

(2A) For the purposes of subsection (2), *listed provision* means:

- (a) subsection (5) or (5A); or
- (b) a determination under paragraph (7A)(b); or
- (c) subsection 99ACF(1) or (2) because of item 4A, 4B or 8 in the table in subsection 99ACF(1); or
- (d) section 99ACQ; or
- (e) subsection 99ACR(3) or (4); or
- (f) repealed section 99ACE.

43 Subsection 99ACD(4) (heading)

Omit “25%”, substitute “*First new brand*”.

44 Paragraphs 99ACD(4A)(c) and (d)

Omit “15%”, substitute “35%”.

45 Paragraph 99ACD(4A)(d)

Omit “40%”, substitute “60%”.

46 Subsection 99ACD(4A) (note)

Omit “40%”, substitute “60%”.

47 After subsection 99ACD(4A)

Insert:

- (4B) If the approved ex-manufacturer price mentioned in paragraph (4A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

48 Subsection 99ACD(5A)

Omit “(7B)”, substitute “(7A)”.

49 Paragraphs 99ACD(5A)(a) and (b)

Omit “60%”, substitute “40%”.

50 After subsection 99ACD(5A)

Insert:

- (5B) If the approved ex-manufacturer price mentioned in paragraph (5A)(a) or (b) is by reference to a different pricing quantity than the pricing quantity on the day before the determination day, the approved ex-manufacturer price mentioned in that paragraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the day before the determination day.

51 Subsections 99ACD(7A) and (7B)

Repeal the subsections, substitute:

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (7A) The Minister may, by notifiable instrument, determine that:
- (a) the agreed price of the new brand of the trigger combination item that comes into force on the determination day is to be equal to the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item; or
 - (b) the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed the approved ex-manufacturer price, on the day before the determination day, of the existing brand of the existing item, reduced by a lower percentage than would otherwise result from the operation of subsection (5) or (5A) in relation to the determination day.

(7B) If the Minister makes a determination under paragraph (7A)(a), subsections (5) and (5A) are taken not to have applied to the trigger combination item.

52 Subsection 99ACD(7C)

Omit “or (7B)”.

53 Subsection 99ACD(7D)

Repeal the subsection.

54 Section 99ACE

Repeal the section.

55 Subsection 99ACF(1)

Omit “section 99ACG”, substitute “sections 99ACG and 99ADHC”.

56 Subsection 99ACF(1)

After “subject to subsections”, insert “(1A),”.

57 Subsection 99ACF(1) (after table item 2)

Insert:

2A	99ACHB	5%
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58 Subsection 99ACF(1) (after table item 3)

Insert:

3A	99ACJA	5%
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59 Subsection 99ACF(1) (after table item 4)

Insert:

4A	99ACKA	26.1%
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4B	99ACKB	30%
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60 Subsection 99ACF(1) (at the end of the table)

Add:

7	99ACM	5%
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8	99ACN	The percentage referred to in paragraph 99ACN(1)(c)
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9	99ACP	1.48%
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61 After subsection 99ACF(1)

Insert:

Reduction cap

(1A) If:

- (a) the approved ex-manufacturer price of a listed brand of a pharmaceutical item is to be reduced under subsection (1) because of an item in the table in subsection (1); and
- (b) apart from this subsection, the reduced approved ex-manufacturer price would be less than the amount (the ***capped price***) equal to:
 - (i) 40% of the approved ex-manufacturer price of a listed brand of the pharmaceutical item on 1 January 2016; or
 - (ii) if subparagraph (i) does not apply—40% of the original approved ex-manufacturer price of the first listed brand of the pharmaceutical item;

the approved ex-manufacturer price of the listed brand of the pharmaceutical item is taken to be reduced under subsection (1) because of that item to an amount equal to the capped price.

(1B) If the approved ex-manufacturer price mentioned in subparagraph (1A)(b)(i) or (ii) is by reference to a different pricing quantity than the pricing quantity on the reduction day, the approved ex-manufacturer price mentioned in that subparagraph is taken to be the amount that the approved ex-manufacturer price would have been had the pricing quantity been the same as the pricing quantity on the reduction day.

62 Paragraph 99ACF(2)(b)

Repeal the paragraph, substitute:

- (b) subject to subsection (2A), on the reduction day, the approved ex-manufacturer price of the listed brand of the pharmaceutical item does not exceed:
 - (i) the approved ex-manufacturer price of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or

method specified in column 3 of the table for the section or subsection referred to in column 2; or

- (ii) if subsection (1A) would have applied to the brand of the pharmaceutical item if paragraph (1)(b) were disregarded—the capped price of the brand of the pharmaceutical item that would be worked under subsection (1A) if paragraph (1)(b) were disregarded; and

63 Subsections 99ACF(2AA) to (2AC)

Repeal the subsections.

64 Subsection 99ACF(2A)

Omit “, paragraph (2)(b) and subsections (2AB) and (2AC)”, substitute “and paragraph (2)(b)”.

64A Subsection 99ACF(3)

Omit “written instrument”, substitute “notifiable instrument”.

65 Paragraphs 99ACF(3)(a) and (b)

Omit “items 2 to 6”, substitute “an item”.

66 Subsections 99ACF(3AA) and (3AB)

Repeal the subsections.

67 Subsection 99ACF(3A)

Omit “, or subsection (2AB) or paragraphs (2AC)(a) and (b)”.

68 Subsection 99ACF(3B)

Omit “, (3AA) or (3AB)”.

69 Subparagraph 99ACG(b)(ii)

Omit “or 99ACE”.

70 Subparagraphs 99ACG(b)(iii) and (iv)

Repeal the subparagraphs, substitute:

- (iii) subsection 99ACF(1) or (2) because of item 4A, 4B, 7, 8 or 9 in the table in subsection 99ACF(1);

- (iv) section 99ACQ;
- (v) subsection 99ACR(3) or (4);

71 Section 99ACH

Repeal the section.

72 Paragraph 99ACHA(1)(c)

Before “section 99ACH”, insert “repealed”.

73 After section 99ACHA

Insert:

99ACHB 5% statutory price reduction for drugs on F1—fifth anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
 - (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
 - (b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and
 - (c) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
 - (d) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced:
 - (i) under subsection 99ACF(1) or (2); or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3).
 - (2) In this section, each of the following is a **5% price reduction day**:
 - (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;
 - (d) 1 April 2026;
 - (e) 1 April 2027.
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74 After section 99ACJ

Insert:

99ACJA 5% statutory price reduction for drugs on F1—tenth anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
 - (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
 - (b) the 5% price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 3 in the table in section 99ACF; or
 - (ii) item 3A in the table in section 99ACF; or
 - (iii) item 5 in the table in section 99ACF; or
 - (iv) item 7 in the table in section 99ACF; and
 - (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item; and
 - (e) on or before the 5% price reduction day, the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced:
 - (i) because of repealed section 99ACE or repealed section 99ACH; or
 - (ii) under section 99ACQ; or
 - (iii) under subsection 99ACR(3).
- (2) In this section, each of the following is a **5% price reduction day**:
 - (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;
 - (d) 1 April 2026;
 - (e) 1 April 2027.

75 After section 99ACK

Insert:

99ACKA 26.1% statutory price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 26.1% price reduction day if:
 - (a) the 26.1% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and
 - (b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 4 in the table in section 99ACF; or
 - (ii) item 4A in the table in section 99ACF; or
 - (iii) item 6 in the table in section 99ACF; or
 - (iv) item 8 in the table in section 99ACF; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 26.1% price reduction day:
 - (i) because of section 99ACB or 99ACD; or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3); and
 - (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 26.1% price reduction day; and
 - (e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

- (2) In this section, each of the following is a **26.1% price reduction day**:
 - (a) 1 April 2023;
 - (b) 1 April 2024;
 - (c) 1 April 2025;

(d) 1 April 2026.

99ACKB 30% statutory price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on the 30% price reduction day if:
- (a) the 30% price reduction day is on or after the 15th anniversary of the drug in the pharmaceutical item being a listed drug; and
 - (b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 4 in the table in section 99ACF; or
 - (ii) item 4A in the table in section 99ACF; or
 - (iii) item 6 in the table in section 99ACF; or
 - (iv) item 8 in the table in section 99ACF; and
 - (c) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been reduced on or before the 30% price reduction day:
 - (i) because of section 99ACB or 99ACD; or
 - (ii) because of repealed section 99ACE or repealed section 99ACH; or
 - (iii) under section 99ACQ; or
 - (iv) under subsection 99ACR(3); and
 - (d) subsection 99ACR(4) has not applied to the brand of the pharmaceutical item on or before the 30% price reduction day; and
 - (e) the pharmaceutical item is not an exempt item.

Note: See also section 99ACG.

(2) In this section, the **30% price reduction day** is 1 April 2027.

76 At the end of Division 3A of Part VII

Add:

99ACM 5% statutory price reduction for drugs on F1—tenth anniversary

- (1) This section applies to a brand of a pharmaceutical item on a 5% price reduction day if:
- (a) the drug in the pharmaceutical item is on F1 on the 5% price reduction day; and
 - (b) the tenth anniversary of the drug being a listed drug occurred during the period:
 - (i) beginning at the start of 1 May 2021; and
 - (ii) ending at the end of 1 April 2022.

Note: See also section 99ACG.

- (2) In this section, the *5% price reduction day* is 1 April 2023.

99ACN Catch-up price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on the catch-up price reduction day if:
- (a) the 15th anniversary of the drug in the pharmaceutical item being a listed drug was on or before 1 April 2022; and
 - (b) the pharmaceutical item is not an exempt item; and
 - (c) on the catch-up price reduction day, the percentage worked out using the formula in subsection (2) is greater than zero.

Note: See also section 99ACG.

- (2) The formula mentioned in paragraph (1)(c) is:

$$100\% - \frac{63.18\%}{\text{Product of differential percentages}}$$

where:

product of differential percentages means:

- (a) if there has been only one previous price reduction under this Division—the differential percentage for that price reduction; or

- (b) if there have been 2 or more previous price reductions under this Division—the product of the differential percentages for those previous price reductions; or
- (c) if there have not been any previous price reductions under this Division—100%.

Note 1: The effect of the formula is that, following the application of the price reduction which applies as a result of this section and item 8 of the table in section 99ACF(1), the cumulative impact of price reductions under this Division, applied successively, will be 36.82%. For example, if the brand of the pharmaceutical item has been subject to a 5% previous price reduction under this Division followed by a 16% previous price reduction under this Division, the product of the differential percentages will be $(100\% - 5\%) \times (100\% - 16\%) = 79.80\%$, and the percentage worked out using the formula will be $100\% - 63.18\%/79.80\% = 20.83\%$.

Note 2: For rounding of the percentage worked out using the formula, see subsection (5).

- (3) For the purposes of this section, ***previous price reduction under this Division*** has the meaning given by section 99ACNA.
- (4) For the purposes of this section, the ***differential percentage*** for a previous price reduction under this Division means the difference between 100% and the previous price reduction under this Division.
- (5) The percentage worked out using the formula in subsection (2) is to be calculated to 2 decimal places (rounding up if the third decimal place is 5 or more).
- (6) In this section, the ***catch-up price reduction day*** is 1 April 2023.

99ACNA Catch-up price reduction for certain drugs—meaning of *previous price reduction under this Division*

- (1) For the purposes of the application of section 99ACN to a brand (the ***relevant brand***) of a pharmaceutical item, ***previous price reduction under this Division*** means:
 - (a) a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under this Division (expressed as a percentage) (other than a reduction attributable to section 99ACN); or

- (b) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACF(2)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACF(1) if paragraph (b) of that subsection were disregarded; or
 - (c) in the case of a reduction, on or before the catch-up price reduction day, in the approved ex-manufacturer price of the relevant brand or another brand of the pharmaceutical item under subsection 99ACR(4)—the reduction in the approved ex-manufacturer price of the relevant brand or the other brand of the pharmaceutical item (expressed as a percentage) that would have occurred under subsection 99ACR(3) if subsection 99ACR(4) did not apply; or
 - (d) a 12.5% administrative price reduction that applied, on or before the catch-up price reduction day, to the relevant brand or another brand of the pharmaceutical item.
- (2) For the purposes of this section:
- (a) a reduction in the agreed price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and
 - (b) a reduction in the determined price of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item; and
 - (c) a reduction before 1 October 2012 in the approved price to pharmacists (within the meaning of this Part as it stood before 1 October 2012) of a brand of the pharmaceutical item is taken to be a reduction in the approved ex-manufacturer price of the brand of the pharmaceutical item.
- (3) A reference in this section to the approved ex-manufacturer price of a brand of a pharmaceutical item being reduced under subsection 99ACR(4) is to be read as a reference to that subsection applying to the brand of the pharmaceutical item.
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- (4) A reference in this section to this Division includes this Division as in force at any time before the commencement of this section.
- (5) In this section, the *catch-up price reduction day* is 1 April 2023.

99ACP 1.48% statutory price reduction for certain drugs—15th anniversary

- (1) This section applies to a brand of a pharmaceutical item on the 15th anniversary price reduction day if:
 - (a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) or section 99ACQ or subsection 99ACR(3) has applied to the brand of the pharmaceutical item; and
 - (b) the approved ex-manufacturer price of the brand of the pharmaceutical item has not been previously reduced under subsection 99ACF(1) or (2) because of:
 - (i) item 4 in the table in section 99ACF; or
 - (ii) item 4A in the table in section 99ACF; or
 - (iii) item 8 in the table in section 99ACF; or
 - (iv) item 9 in the table in section 99ACF; and
 - (c) the item is not an exempt item.

Note: See also section 99ACG.

- (2) In this section, the *15th anniversary price reduction day* is the 15th anniversary of the drug in the pharmaceutical item being listed as a listed drug.

Subdivision E—Flow-on of first new brand price reductions to existing brands and related brands

99ACQ Flow-on of price reductions to existing brands of the same pharmaceutical item

- (1) This section applies to a brand (the *existing brand*) of a pharmaceutical item if:
 - (a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the *new brand*) of the pharmaceutical item; and
 - (b) that price comes into force on a day (the *reduction day*); and

- (c) on the day before the reduction day, the existing brand of the item was a listed brand of the item.

Note: See also section 99ACG.

- (2) On the reduction day, the approved ex-manufacturer price of the existing brand of the item is taken to be reduced to an amount equal to the approved ex-manufacturer price of the new brand.
- (3) If the approved ex-manufacturer price of the existing brand of the item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the item is reduced under subsection (2).

Section does not limit Minister's powers

- (4) This section does not limit the Minister's powers, on or after the reduction day, to make:
- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the existing brand of the item.

99ACR Flow-on of first new brand price reductions to related brands

- (1) This section applies to a brand (the *related brand*) of a pharmaceutical item (a *related item*) mentioned in subsection (2) if:
- (a) subsection 99ACB(5) or (5A) or 99ACD(5) or (5A) has applied to the agreed price for a brand (the *new brand*) of a pharmaceutical item (the *new item*); and
 - (b) that price comes into force on a day (the *reduction day*); and
 - (c) on the day before the reduction day, the related brand of the related item was a listed brand of the related item; and
 - (d) the related item is not an exempt item.

Note: See also section 99ACG.

- (2) For the purposes of this section, a related brand of a related item is any of the following:
-

- (a) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new item;
 - (b) if the drug in the new item is in a therapeutic group—a listed brand of a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the new item.
- (3) Subject to subsections (4) and (6), on the reduction day, the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item is taken to be reduced by a percentage equal to the percentage by which the agreed price for the new brand was reduced as a result of the application of the subsection mentioned in paragraph (1)(a).
- (4) Subsection (3) does not apply to the related brand of the related item if:
- (a) on the reduction day, the approved ex-manufacturer price of the related brand of the related item does not exceed the approved ex-manufacturer price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3); and
 - (b) if there is an applicable claimed price of the related brand of the related item—on the reduction day, the claimed price of the related brand of the related item does not exceed the claimed price of the related brand of the related item in force on the day before the reduction day, reduced by more than the percentage required under subsection (3).

Apportioning if pricing quantity changes

- (5) If the pricing quantity of the related brand of the related item on the day before the reduction day is different from the pricing quantity of the related brand of the related item on the reduction day, then, for the purposes of subsection (3) and paragraph (4)(a), the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day is taken to be the amount worked out using the following formula:

$$\frac{AEMP1}{PQ1} \times PQ2$$

where:

AEMP1 means the amount that was the approved ex-manufacturer price of the related brand of the related item on the day before the reduction day.

PQ1 means the pricing quantity of the related brand of the related item on the day before the reduction day.

PQ2 means the pricing quantity of the related brand of the related item on the reduction day.

Ministerial discretion not to apply, or to reduce, flow-on price reduction

- (6) In relation to the related brand of the related item, the Minister may, by notifiable instrument, determine that:
- (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (3) in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (3) in relation to a particular reduction day.
- (7) If the Minister makes a determination under paragraph (6)(a), subsection (3) is taken not to have applied to the related brand of the related item.
- (8) In making a determination under subsection (6):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the related brand of the related item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account any other matter the Minister thinks is relevant.

Section does not limit Minister's powers

- (9) This section does not limit the Minister's powers, on or after the reduction day, to make:
- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the related brand of the related item.

77 Paragraph 99ADH(1)(c)

Repeal the paragraph, substitute:

- (c) the unadjusted price reduction for the brand of the pharmaceutical item is:
- (i) if section 99ADHC does not apply to the brand of the pharmaceutical item—at least 10%; or
 - (ii) subject to subparagraph (iii), if section 99ADHC applies to the brand of the pharmaceutical item and the approved ex-manufacturer price of the brand of the pharmaceutical item is more than \$4—at least 30%; or
 - (iii) if section 99ADHC applies to the brand of the pharmaceutical item, the approved ex-manufacturer price of the brand of the pharmaceutical item is more than \$4, and the brand of the pharmaceutical item has passed the 12.5% average unadjusted price reduction test set out in subsection (6) of this section—at least 10%.

78 Subsection 99ADH(2A)

Repeal the subsection.

79 At the end of section 99ADH

Add:

12.5% average unadjusted price reduction test

- (6) For the purposes of this section, a brand of a pharmaceutical item passes the **12.5% average unadjusted price reduction test** if there have been 3 consecutive data collection periods in respect of which a weighted average disclosed price has been determined for any brand of the pharmaceutical item, where:

- (a) the percentage obtained by dividing the total of the unadjusted price reductions for a brand of the pharmaceutical item in respect of each of those data collection periods by 3 is at least 12.5%; and
 - (b) this section did not apply to the brand of the pharmaceutical item in relation to any of those data collection periods; and
 - (c) those data collection periods include the data collection period mentioned in paragraph (1)(a).
- (7) For the purposes of subsection (6), if the Minister determines the weighted average disclosed price of a brand of a pharmaceutical item in respect of a data collection period for the brand, the unadjusted price reduction for the brand of the pharmaceutical item in respect of the data collection period is the unadjusted price reduction for the brand of the pharmaceutical item when the determination came into force.

Note: See subsection 99ADB(4).

80 Subsections 99ADHB(2) to (6)

Repeal the subsections, substitute:

Price reduction

- (2) Subject to subsections (6) and (6B), on the reduction day, the approved ex-manufacturer price of the existing brand of the combination item is taken to be reduced in accordance with a method prescribed by the regulations.
- (3) Different methods may be prescribed by the regulations for different classes of combination items.
- (4) Subsection (3) does not limit subsection 33(3A) of the *Acts Interpretation Act 1901*.
- (5) Subject to subsection (6), if the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2), then, on the reduction day, the claimed price (if any) of the existing brand of the combination item is taken to be reduced by a percentage equal to the percentage by which the approved ex-manufacturer price of the existing brand of the combination item is reduced under subsection (2).

Ministerial discretion not to apply, or to reduce, statutory price reduction

- (6) In relation to the existing brand of the combination item, the Minister may, by notifiable instrument, determine that:
- (a) the approved ex-manufacturer price, and (if applicable) the claimed price, is not to be reduced under subsection (2) or (5), as the case requires, in relation to a particular reduction day; or
 - (b) the approved ex-manufacturer price, and (if applicable) the claimed price, is to be reduced by a lower percentage than would otherwise apply under subsection (2) or (5), as the case requires, in relation to a particular reduction day.
- (6A) In making a determination under subsection (6):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) the claimed price, of the existing brand of the combination item would otherwise be under this section in relation to the particular reduction day if a determination were not made; and
 - (b) the Minister may take into account:
 - (i) any advice given to the Minister under subsection 101(4AC) in relation to the combination item; and
 - (ii) any other matter the Minister thinks is relevant.
- (6B) If the Minister makes a determination under subsection (6), the approved ex-manufacturer price of the existing brand of the combination item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the determination made under subsection (6).

Section does not limit Minister's powers

- (6C) This section does not limit the Minister's powers, on or after the reduction day, to make:
- (a) further price agreements; or
 - (b) determinations under section 85B;
- for the existing brand of the combination item.

81 Subsections 99ADHB(8) to (12)

Repeal the subsections.

82 After Division 3B of Part VII

Insert:

Division 3BA—Floor price of a brand of a pharmaceutical item

99ADHC Floor price of a brand of a pharmaceutical item

When this section applies

- (1) Subject to subsection (3), this section applies to a brand (the *designated brand*) of a pharmaceutical item if:
 - (a) both:
 - (i) the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months; and
 - (ii) at the end of the previous data collection period for the designated brand of the pharmaceutical item, at least 30 months have passed since the first price reduction under Division 3B of any listed brand of a pharmaceutical item that has the same drug and manner of administration of the pharmaceutical item; or
 - (b) the approved ex-manufacturer price of the designated brand of the pharmaceutical item is \$4 or less; or
 - (c) both:
 - (i) the approved ex-manufacturer price of a brand of the pharmaceutical item has been increased on or after 1 July 2022 as a result of the making of a price agreement; and
 - (ii) a determination is in force under subsection (2) in relation to the designated brand of the pharmaceutical item; or
 - (d) the approved ex-manufacturer price of the designated brand of the pharmaceutical item has been increased under section 104B.
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Note: Section 104B commences on 1 October 2022.

- (2) If the approved ex-manufacturer price of a brand of a pharmaceutical item is increased on or after 1 July 2022 as a result of a new agreed price coming into force, the Minister may, by notifiable instrument, determine that paragraph (1)(c) applies to the brand of the pharmaceutical item.
- (3) This section does not apply to a brand of a pharmaceutical item if:
 - (a) the drug in the pharmaceutical item is included in Schedule 2 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989* and as in force from time to time) by reference to a quantity or amount of the drug; and
 - (b) that quantity or amount of the drug is equal to or greater than the total quantity or amount of the drug contained in the quantity or number of units of the brand of the pharmaceutical item in any pack quantity of the brand of the pharmaceutical item.

Limits on price reductions

- (4) The approved ex-manufacturer price of the designated brand of the pharmaceutical item is not to be reduced under this Part unless:
 - (a) the reduction is the result of the making of a price agreement; or
 - (b) the reduction is under section 99ADH as the result of subparagraph 99ADH(1)(c)(ii) or (iii).
- (5) If, apart from this subsection:
 - (a) the approved ex-manufacturer price of the designated brand of the pharmaceutical item is to be reduced under a provision of this Part; and
 - (b) the reduction would result in the approved ex-manufacturer price being less than \$4;then:
 - (c) the approved ex-manufacturer price is not to be reduced under that provision to an amount less than \$4; and
 - (d) the approved ex-manufacturer price is instead to be reduced by an amount that would result in the approved ex-manufacturer price being \$4; and

- (e) the reduction mentioned in paragraph (d) is taken to be a reduction under that provision.

When the drug and manner of administration of a pharmaceutical item is taken to have been on F2 for at least 42 months

- (6) For the purposes of paragraph (1)(a), the drug and manner of administration of a pharmaceutical item is taken to have been on F2 for at least 42 months if:
- (a) at end of the previous data collection period, the drug in the designated brand of the pharmaceutical item had been on F2 for at least 42 months; and
 - (b) on a day at least 42 months before the end of the previous data collection period:
 - (i) there was a related brand of the designated brand of the pharmaceutical item that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the designated brand of the pharmaceutical item; or
 - (ii) there were 2 or more related brands of the designated brand of the pharmaceutical item that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.
- (7) For the purposes of this section, *data collection period* has the same meaning as in Division 3B.

83 Paragraphs 99AEI(3)(a) and (b)

Repeal the paragraphs, substitute:

- (a) if subsection 99ACB(5) applied to the delisted brand of the existing item—for the purposes of subsection 99ACB(3), subsection 99ACB(5) is taken not to have applied to the delisted brand of the existing item; or
 - (b) if subsection 99ACB(5A) applied to the delisted brand of the existing item—for the purposes of subsection 99ACB(3), subsection 99ACB(5A) is taken not to have applied to the delisted brand of the existing item; or
 - (c) if subsection 99ACD(5) applied to the delisted brand of the existing item—for the purposes of subsection 99ACD(2), subsection 99ACD(5) is taken not to have applied to the delisted brand of the existing item; or
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- (d) if subsection 99ACD(5A) applied to the delisted brand of the existing item—for the purposes of subsection 99ACD(2), subsection 99ACD(5A) is taken not to have applied to the delisted brand of the existing item.

Part 3—Amendments commencing on 1 October 2022

National Health Act 1953

84 After Division 3C of Part VII

Insert:

Division 3CA—Discounts and incentives

99AEL Minister’s powers if responsible person offers discounts or incentives for certain brands of pharmaceutical items

When this section applies

- (1) This section applies if:
 - (a) a brand of a pharmaceutical item has an approved ex-manufacturer price of \$4 or less; and
 - (b) the responsible person offers a discount or incentive, in relation to sales of the brand of the pharmaceutical item, on one or more occasions; and
 - (c) section 99ADHC applies to the brand of the pharmaceutical item.

Minister’s powers

- (2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:
 - (a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the brand of the pharmaceutical item;
 - (b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;

- (d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:
 - (i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or
 - (ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or
 - (iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the brand referred to in subsection (1), or a pharmaceutical item mentioned in those paragraphs may be the item referred to in subsection (1).

- (3) In exercising a power under subsection (2), the Minister must have regard to any relevant information that:
 - (a) relates to discounts or incentives; and
 - (b) was disclosed in compliance with the price disclosure requirements referred to in Division 3B.
- (4) In exercising a power under subsection (2), the Minister may have regard to the following:
 - (a) the extent to which the discount or incentive will compromise the responsible person’s capacity to continue to supply the brand of the pharmaceutical item;
 - (b) whether the responsible person will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future;
 - (c) the extent to which the discount or incentive will compromise another person’s capacity to continue to supply another brand of the pharmaceutical item;
 - (d) any other matter the Minister thinks is relevant.
- (5) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Meaning of discount or incentive

- (6) For the purposes of this section, **discount or incentive**, in relation to sales of a brand of a pharmaceutical item, means:

- (a) anything that results in the net revenue for the brand of the pharmaceutical item for a data collection period for the brand of the pharmaceutical item falling below the amount that would have been the net revenue for the brand of the pharmaceutical item for the data collection period if the price charged for the brand of the pharmaceutical item had been equal to the approved ex-manufacturer price of the brand of the pharmaceutical item; or
 - (b) an incentive given in relation to sales of the brand of the pharmaceutical item.
- (7) For the purposes of subsection (6), *incentive* and *net revenue* have the same respective meanings as they have when used in regulations made for the purposes of subsection 99ADB(6).
- (8) For the purposes of subsection (6), *data collection period* has the same meaning as in Division 3B.

85 After section 104A

Insert:

104B Transitional—price increases on 1 October 2022

When this section applies

- (1) Subject to subsections (2) and (3), this section applies to a brand of a pharmaceutical item if, immediately before the start of 1 October 2022:
- (a) the drug in the brand of the pharmaceutical item was on F2; and
 - (b) the brand of the pharmaceutical item had an approved ex-manufacturer price that is less than \$3.50.
- (2) The Minister may, by writing, determine that this section does not apply in relation to all brands of a specified pharmaceutical item.
- (3) This section does not apply to a brand of a pharmaceutical item if:
- (a) the drug in the pharmaceutical item is included in Schedule 2 to the current Poisons Standard (within the meaning of the *Therapeutic Goods Act 1989* and as in force from time to time) by reference to a quantity or amount of the drug; and

- (b) that quantity or amount of the drug is equal to or greater than the total quantity or amount of the drug contained in the quantity or number of units of the brand of the pharmaceutical item in any pack quantity of the brand of the pharmaceutical item.

Price increases

- (4) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of \$2 or less, the approved ex-manufacturer price is taken to be increased to \$2.50 at the start of 1 October 2022.
- (5) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of more than \$2 but not more than \$3, the approved ex-manufacturer price is taken to be increased by 50 cents at the start of 1 October 2022.
- (6) Subject to subsection (7), if, on the day before 1 October 2022, the brand of the pharmaceutical item had an approved ex-manufacturer price of more than \$3 but less than \$3.50, the approved ex-manufacturer price is taken to be increased to \$3.50 at the start of 1 October 2022.

Apportioning if pricing quantity changes

- (7) If the pricing quantity of the brand of the pharmaceutical item on the day before 1 October 2022 is more than the pricing quantity of the brand of the pharmaceutical item on 1 October 2022, then the approved ex-manufacturer price of the brand of the pharmaceutical item on 1 October 2022 is taken to be the amount worked out using the following formula:

$$\frac{AEMPI}{PQ1} \times PQ2$$

where:

AEMPI means the amount the approved ex-manufacturer price of the brand of the pharmaceutical item would be on 1 October 2022 if the pricing quantity had not changed.

Schedule 1 Amendments

Part 3 Amendments commencing on 1 October 2022

PQ1 means the pricing quantity of the brand of the pharmaceutical item on the day before 1 October 2022.

PQ2 means the pricing quantity of the brand of the pharmaceutical item on 1 October 2022.

Section does not limit Minister's powers

- (8) This section does not limit the Minister's powers, on or after 1 October 2022, to make:
- (a) price agreements; or
 - (b) determinations under section 85B;
- in relation to the brand of the pharmaceutical item.

Part 4—Amendments commencing on 1 July 2023

National Health Act 1953

86 After Division 3C of Part VII

Insert:

Division 3CAA—Minimum stockholding requirement

99AEKA Brands subject to the minimum stockholding requirement

For the purposes of this Division, a brand of a pharmaceutical item is subject to the minimum stockholding requirement if section 99ADHC applies to the brand of the pharmaceutical item.

99AEKB Minimum stockholding requirement

- (1) If a brand of a pharmaceutical item is subject to the minimum stockholding requirement, the responsible person for the brand of the pharmaceutical item must keep in stock in Australia at least the applicable quantity of the brand of the pharmaceutical item.
- (2) For the purposes of this Division, if a quantity of a brand of a pharmaceutical item is not available for sale in Australia by the responsible person, that quantity of the brand of the pharmaceutical item is taken not to be kept in stock.

99AEKC Applicable quantity of a brand of a pharmaceutical item

- (1) For the purposes of this Division, the *applicable quantity* of a brand of a pharmaceutical item is:
 - (a) if the approved ex-manufacturer price of the brand of the pharmaceutical item has not been increased on or after 1 July 2022:
 - (i) 4 months stock by reference to usual demand for the brand of the pharmaceutical item; or
 - (ii) if another quantity is ascertained in accordance with a determination under subsection (2)—that quantity; or

- (b) if the approved ex-manufacturer price of the brand of the pharmaceutical item was increased on or after 1 July 2022:
 - (i) 6 months stock by reference to usual demand for the brand of the pharmaceutical item; or
 - (ii) if another quantity is ascertained in accordance with a determination under subsection (2)—that quantity.
- (2) The Minister may, by legislative instrument, make a determination for the purposes of either or both of the following:
 - (a) subparagraph (1)(a)(ii);
 - (b) subparagraph (1)(b)(ii).
- (3) A quantity ascertained in accordance with a determination under subsection (2) may be a specified number of months stock by reference to usual demand for the brand of the pharmaceutical item.
- (4) Subsection (3) does not limit subsection (2).
- (5) For the purposes of this section, *usual demand* for a brand of a pharmaceutical item is to be ascertained in accordance with the regulations.

99AEKD Minister to be notified of breach of minimum stockholding requirements

Notification of likely breach of the minimum stockholding requirement

- (1) If:
 - (a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and
 - (b) the responsible person for the brand of the pharmaceutical item forms the belief that the person is likely to breach section 99AEB in relation to the brand of the pharmaceutical item;the person must:
 - (c) give the Minister a written notice that:
 - (i) informs the Minister of that belief; and
 - (ii) sets out the person's reasons for that belief; and

(d) do so as soon as practicable after forming that belief.

Notification of breach of the minimum stockholding requirement

- (2) If:
- (a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and
 - (b) the responsible person for the brand of the pharmaceutical item has breached section 99AEKB in relation to the brand of the pharmaceutical item;
- the person must:
- (c) give the Minister a written notice that:
 - (i) informs the Minister of the breach; and
 - (ii) sets out the person's reasons for the breach; and
 - (d) do so as soon as practicable after the breach.

Offence

- (3) A person commits an offence if:
- (a) the person is subject to a requirement under subsection (1) or (2); and
 - (b) the person omits to do an act; and
 - (c) the omission breaches the requirement.

Penalty: 60 penalty units.

- (4) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (3) of this section.

99AEKE Minister's power if responsible person breaches minimum stockholding requirement

- (1) This section applies if:
- (a) a brand of a pharmaceutical item is subject to the minimum stockholding requirement; and
 - (b) the responsible person for the brand of the pharmaceutical item has breached section 99AEKB in relation to the brand of the pharmaceutical item.

- (2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:
- (a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the brand of the pharmaceutical item;
 - (b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:
 - (i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or
 - (ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or
 - (iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.
- Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the brand referred to in subsection (1), or a pharmaceutical item mentioned in those paragraphs may be the item referred to in subsection (1).
- (3) In exercising a power under subsection (2), the Minister must have regard to the following:
- (a) both:
 - (i) the responsible person's reasons for the breach; and
 - (ii) whether those reasons are, in the Minister's opinion, reasonable;
 - (b) whether, in the Minister's opinion, the responsible person will consistently maintain adequate stock levels of the brand of the pharmaceutical item in the future;
 - (c) whether the responsible person for the brand of the pharmaceutical item has offered discounts or incentives in relation to sales of the brand of the pharmaceutical item;

- (d) whether the responsible person for the brand of the pharmaceutical item has previously breached section 99AEKB and, if so:
 - (i) the person's reasons for the breach; and
 - (ii) whether those reasons are, in the Minister's opinion, reasonable;
 - (e) whether the responsible persons for other brands of the pharmaceutical item have breached section 99AEKB in relation to those other brands of the pharmaceutical item;
 - (f) any other matter the Minister thinks is relevant.
- (4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.
- (5) For the purposes of this section, *discount or incentive* has the same meaning as in section 99AEL.

99AEKF Stockholding disclosure requirements

- (1) The *stockholding disclosure requirements* for a brand of a pharmaceutical item are:
- (a) to provide information prescribed by the regulations in relation to the quantity of the brand of the pharmaceutical item kept in stock in Australia by the responsible person for the brand of the pharmaceutical item; and
 - (b) to provide that information in the manner and form prescribed by the regulations; and
 - (c) to provide that information at the times prescribed by the regulations.

When the stockholding disclosure requirements apply

- (2) If a brand of a pharmaceutical item is subject to the minimum stockholding requirement, the responsible person for the brand of the pharmaceutical item is required to comply with the stockholding disclosure requirements for the brand of the pharmaceutical item.

Offence for failing to comply with the stockholding disclosure requirements

- (3) A person commits an offence if:
- (a) the person is required to comply with the stockholding disclosure requirements for a brand of a pharmaceutical item; and
 - (b) the person fails to comply with those requirements for the brand of the pharmaceutical item.

Penalty: 60 penalty units.

- (4) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (3) of this section.

87 After paragraph 99AEL(4)(b)

Insert:

- (ba) whether the responsible person has breached section 99AEKB;

Part 5—Amendments commencing on 1 July 2027

National Health Act 1953

87A Subsection 85AB(4A)

Repeal the subsection.

88 Subsection 99ACB(1)

Omit “, (3), (3A) and (3B)”, substitute “and (3)”.

89 Paragraph 99ACB(2)(c)

Omit “applied; or”, substitute “applied.”.

90 Paragraph 99ACB(2)(d)

Repeal the paragraph.

91 Subsection 99ACB(2A)

Repeal the subsection.

92 Subparagraph 99ACB(3)(a)(i)

Omit “or (5A)”.

93 Subsection 99ACB(3) (note)

Omit “subsections (5) and (5A) of this section are”, substitute “subsection (5) of this section is”.

94 Subsections 99ACB(3A) and (3B)

Repeal the subsections.

95 Subsections 99ACB(4A) and (4B)

Repeal the subsections.

96 Subsection 99ACB(5)

Omit “25%”, substitute “16%”.

97 Subsections 99ACB(5A) and (5B)

Repeal the subsections.

98 Subsection 99ACB(6)

Omit “subsections (5) and (5A)”, substitute “subsection (5)”.

99 Paragraph 99ACB(6A)(b)

Omit “or (5A)”.

100 Subsection 99ACB(6B)

Omit “subsections (5) and (5A) are”, substitute “subsection (5) is”.

100A Section 99ACBA

Repeal the section.

101 Subsection 99ACC(2)

Omit “(5A),”.

102 Subsection 99ACC(5)

Omit “subsections (5A) and (5C)”, substitute “subsection (5C)”.

103 Subsections 99ACC(5A) and (5B)

Repeal the subsections.

104 Subsection 99ACD(1)

Omit “, (2) and (3)”, substitute “and (2)”.

105 Paragraph 99ACD(1A)(c)

Omit “applied; or”, substitute “applied.”.

106 Paragraph 99ACD(1A)(d)

Repeal the paragraph.

107 Subsection 99ACD(1B)

Repeal the subsection.

108 Subsection 99ACD(2) (note)

Omit “subsections (5) and (5A) of this section are”, substitute “subsection (5) of this section is”.

109 Paragraph 99ACD(2A)(a)

Omit “or (5A)”.

110 Subsection 99ACD(3)

Repeal the subsection.

111 Subsections 99ACD(4A) and (4B)

Repeal the subsections.

112 Subsection 99ACD(5)

Omit “25%”, substitute “16%”.

113 Subsections 99ACD(5A) and (5B)

Repeal the subsections.

114 Subsection 99ACD(7)

Omit “subsections (5) and (5A)”, substitute “subsection (5)”.

115 Paragraph 99ACD(7A)(b)

Omit “or (5A)”.

116 Subsection 99ACD(7B)

Omit “subsections (5) and (5A) are”, substitute “subsection (5) is”.

116A Section 99ACEA

Repeal the section.

117 Subsection 99ACF(1)

Omit “(1A),”.

118 Subsection 99ACF(1) (table item 9)

Repeal the item.

119 Subsections 99ACF(1A) and (1B)

Repeal the subsections.

120 Section 99ACP

Repeal the section.

121 Paragraph 99ACQ(1)(a)

Omit “or (5A)” (wherever occurring).

122 Paragraph 99ACR(1)(a)

Omit “or (5A)” (wherever occurring).

123 Paragraph 99AEI(3)(b)

Repeal the paragraph.

124 Paragraph 99AEI(3)(c)

Omit “item; or”, substitute “item.”.

125 Paragraph 99AEI(3)(d)

Repeal the paragraph.

126 Subsection 101(4AD)

Repeal the subsection.

*[Minister’s second reading speech made in—
House of Representatives on 28 October 2021
Senate on 30 November 2021]*

(139/21)
