



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

**No. 1, 2018**

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

Note: An electronic version of this Act is available on the Federal Register of Legislation  
(<https://www.legislation.gov.au/>)



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

**No. 1, 2018**

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

[Assented to 20 February 2018]

The Parliament of Australia enacts:

## **1 Short title**

This Act is the *National Health Amendment (Pharmaceutical  
Benefits—Budget and Other Measures) Act 2018*.

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*No. 1, 2018*

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

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## 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.

<b>Commencement information</b>		
<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Provisions</b>	<b>Commencement</b>	<b>Date/Details</b>
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	20 February 2018
2. Schedule 1, Part 1	1 October 2018.	1 October 2018
3. Schedule 1, Part 2	1 July 2022.	1 July 2022
4. Schedule 2, Part 1	The day after this Act receives the Royal Assent.	21 February 2018
5. Schedule 2, Part 2	1 July 2022.	1 July 2022
6. Schedule 3, Part 1	The day after this Act receives the Royal Assent.	21 February 2018
7. Schedule 3, Part 2	1 July 2022.	1 July 2022
8. Schedule 4, Part 1	The day after this Act receives the Royal Assent.	21 February 2018
9. Schedule 4, Part 2	1 July 2022.	1 July 2022
10. Schedules 5 to 9	The day after this Act receives the Royal Assent.	21 February 2018

Note: This table relates only to the provisions of this Act as originally enacted.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.

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- (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—Price reductions for new brands of pharmaceutical items

### Part 1—25% price reduction

#### *National Health Act 1953*

##### **1 Subsection 84(1)**

Repeal the following definitions:

- (a) definition of *subject to a 12.5% price reduction*;
- (b) definition of *subject to a 16% price reduction*.

##### **2 Subsection 84(1)**

Insert:

*12.5% price reduction*: see subsection 99ACA(2).

*16% price reduction*: see subsection 99ACA(2A).

*25% price reduction*: see subsection 99ACA(2B).

##### **3 Section 99AC**

Omit “16% price reduction” (wherever occurring), substitute “25% price reduction”.

##### **4 Subsections 99ACA(2) and (2A)**

Repeal the subsections, substitute:

- (2) A listed component drug contained in a drug in a combination item has been subject to a *12.5% price reduction* if a pharmaceutical item that has:
  - (a) the listed component drug; and
  - (b) the same manner of administration as the combination item;is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied.



- (2A) A listed component drug contained in a drug in a combination item has been subject to a **16% price reduction** if a pharmaceutical item that has:
- (a) the listed component drug; and
  - (b) the same manner of administration as the combination item;
- is in a class of pharmaceutical items to which a 16% administrative price reduction has applied.
- (2B) A listed component drug contained in a drug in a combination item has been subject to a **25% price reduction** if a pharmaceutical item that has:
- (a) the listed component drug; and
  - (b) the same manner of administration as the combination item;
- is in a class of pharmaceutical items to which a 25% administrative price reduction has applied.

#### **5 Subdivision B of Division 3A of Part VII (heading)**

Repeal the heading, substitute:

#### **Subdivision B—25% price reductions for new brands of pharmaceutical items that are not combination items**

#### **6 Section 99ACB (heading)**

Repeal the heading, substitute:

#### **99ACB 25% price reduction for new brands of pharmaceutical items that are not combination items**

#### **7 Paragraphs 99ACB(2)(a), (b) and (c)**

Omit “or 16%”, substitute “, 16% or 25%”.

#### **8 At the end of subsection 99ACB(2)**

Add:

- ; or (d) on the day before the determination day:
- (i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

**Schedule 1** Price reductions for new brands of pharmaceutical items

**Part 1** 25% price reduction

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- (ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;  
has, by virtue of previous price reductions, been reduced by 40% or more.

**9 Subparagraph 99ACB(3)(a)(ii)**

Omit “item 1 of the table in section 99ACF”, substitute “section 99ACH”.

**10 At the end of paragraph 99ACB(3)(a)**

Add:

- (iii) subsection 99ACF(2AB) or (2AC);

**11 Subsection 99ACB(4) (heading)**

Repeal the heading, substitute:

*25% price reduction*

**12 Subsection 99ACB(5)**

Repeal the subsection, substitute:

- (4A) If, on the day before the determination day:
    - (a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
    - (b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;  
has, by virtue of previous price reductions, been reduced by:
      - (c) 15% or less, subsection (5) applies; and
      - (d) more than 15% but less than 40%, subsection (5A) applies.

Note: If previous price reductions have been 40% or more, see paragraph (2)(d).
  - (5) Subject to subsections (6) and (6A), 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 25%.
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- (5A) Subject to subsections (6) and (6B), the agreed price of the new brand of the trigger item that comes into force on the determination day must not exceed:
- (a) 60% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or
  - (b) if paragraph (a) does not apply—60% of the original approved ex-manufacturer price of the first listed brand of the existing item.

### **13 Subsection 99ACB(6)**

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

### **14 After subsection 99ACB(6)**

Insert:

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

- (6A) For the purposes of subsection (5), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price mentioned in that subsection is to be worked out using a lower percentage (including zero %) specified in the determination.
- (6B) For the purposes of paragraphs (5A)(a) and (b), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price mentioned in those paragraphs is to be worked out using a higher percentage specified in the determination.
- (6C) In making a determination under subsection (6A) or (6B):
- (a) the Minister must take into account what the agreed price of the new brand of the trigger item would otherwise be under this section in relation to the particular determination day if a determination were not made; and
  - (b) the Minister may take into account any other matter that the Minister considers relevant.
- (6D) If the Minister makes a determination under subsection (6A) or (6B), the agreed price of the new brand of the trigger item is not to be further reduced under this section on any determination day that

occurs after the determination day specified in the determination made under the relevant subsection.

### **15 At the end of subsection 99ACC(4A)**

Add:

- ; and (e) to the extent that the single brand of the combination item contains one or more component drugs that are not listed component drugs—must take into account the matters mentioned in paragraph (d) in relation to each component drug that is not a listed component drug (the *non-listed component drug*) as if:
- (i) in the case of one non-listed component drug—a declaration under subsection 85(2) was in force in relation to the non-listed component drug on the day the declaration under subsection 85(2) came into force in relation to the listed component drug, or if there is more than one listed component drug, the first listed component drug, of the single brand of the combination item; and
  - (ii) in the case of more than one component drug that is a non-listed component drug—a declaration under subsection 85(2) was in force in relation to each non-listed component drug on the day the declaration under subsection 85(2) came into force in relation to the listed component drug, or if there is more than one listed component drug, the first listed component drug, of the single brand of the combination item.

### **16 Subsection 99ACC(4B)**

Repeal the subsection, substitute:

- (4B) If subsection (4) does not apply, then, in agreeing the new price of the single brand of the combination item, the Minister must take into account:
- (a) in relation to the listed component drug, or each listed component drug, that became subject to statutory price reduction:

- (i) the approved ex-manufacturer price, on the reduction day, of each brand of a pharmaceutical item that has the drug that is the listed component drug; and
  - (ii) the quantity of the listed component drug contained in the combination item; and
- (b) to the extent that the single brand of the combination item contains one or more component drugs that are not listed component drugs—the matters mentioned in paragraph (a) in relation to each component drug that is not a listed component drug as if a declaration under subsection 85(2) was in force in relation to each non-listed component drug, as described in paragraph (4A)(e).

## **17 Subsection 99ACC(6)**

Repeal the subsection, substitute:

*Subject to statutory price reduction etc.*

- (6) The following provisions have effect:
- (a) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if section 99ACB or 99ADH, or subsection 99ACF(1), (2), (2AB) or (2AC) because of section 99ACH, has applied to a listed brand of a pharmaceutical item that:
    - (i) has the listed component drug; and
    - (ii) has the same manner of administration as the combination item;
  - (b) whichever provision mentioned in paragraph (a) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that:
    - (i) has the listed component drug; and
    - (ii) has the same manner of administration as the combination item;
  - (c) a listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if subsection 99ACF(1) or (2) because of item 2, 3, 4, 5 or 6 in

the table in section 99ACF has applied to a listed brand of a pharmaceutical item that has the listed component drug;

- (d) whichever provision mentioned in paragraph (c) applied, that provision applies to the listed component drug contained in the drug in the combination item in the same way as that provision applies to the listed brand of the pharmaceutical item that has the listed component drug.

**18 Section 99ACD (heading)**

Repeal the heading, substitute:

**99ACD 25% price reduction for new brands of combination items**

**19 Paragraphs 99ACD(1A)(a), (b) and (c)**

Omit “or 16%”, substitute “, 16% or 25%”.

**20 At the end of subsection 99ACD(1A)**

Add:

; or (d) on the day before the determination day:

- (i) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or  
(ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by 40% or more.

**21 Subsection 99ACD(4) (heading)**

Repeal the heading, substitute:

*25% price reduction*

**22 Subsections 99ACD(5), (6), (6A) and (6B)**

Repeal the subsections, substitute:

(4A) If, on the day before the determination day:

- (a) the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed brand of the existing item;

has, by virtue of previous price reductions, been reduced by:

(c) 15% or less, subsection (5) applies; and

(d) more than 15% but less than 40%, subsection (5A) applies.

Note: If previous price reductions have been 40% or more, see paragraph (1A)(d).

(5) Subject to subsections (7) and (7A), 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 25%.

(5A) Subject to subsections (7) and (7B), the agreed price of the new brand of the trigger combination item that comes into force on the determination day must not exceed:

(a) 60% of the approved ex-manufacturer price of a listed brand of the existing item on 1 January 2016; or

(b) if paragraph (a) does not apply—60% of the original approved ex-manufacturer price of the first listed brand of the existing item.

### **23 Subsection 99ACD(7)**

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

### **24 After subsection 99ACD(7)**

Insert:

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

(7A) For the purposes of subsection (5), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price mentioned in that subsection is to be worked out using a lower percentage (including zero %) specified in the determination.

(7B) For the purposes of paragraphs (5A)(a) and (b), the Minister may, by written instrument, determine that the relevant approved

ex-manufacturer price mentioned in those paragraphs is to be worked out using a higher percentage specified in the determination.

- (7C) In making a determination under subsection (7A) or (7B):
- (a) the Minister must take into account what the agreed price of the new brand of the trigger combination item would otherwise be under this section in relation to the particular determination day if a determination were not made; and
  - (b) the Minister may take into account any other matter that the Minister considers relevant.
- (7D) If the Minister makes a determination under subsection (7A) or (7B), the agreed price of the new brand of the trigger combination item is not to be further reduced under this section on any determination day that occurs after the determination day specified in the determination made under the relevant subsection.

## **25 Section 99ACE (heading)**

Repeal the heading, substitute:

### **99ACE Flow-on of 25% price reduction to related brands of combination items**

## **26 After subsection 99ACE(1)**

Insert:

- (1A) If paragraph 99ACD(1A)(d) has applied in relation to a new brand of a new combination item, then this section applies to the related brand of the related item as if:
- (a) section 99ACD had applied to the new brand of the new combination item; and
  - (b) the current price for the new brand of the new combination item is the new agreed price; and
  - (c) the day that paragraph 99ACD(1A)(d) is satisfied is the same day as the reduction day.



*Circumstances in which section does not apply*

- (1B) This section does not apply in relation to the related brand of the related item if, on the day before the reduction day:
- (a) the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the first listed related brand of the related item;
- has, by virtue of previous price reductions, been reduced by 40% or more.

**27 Subsection 99ACE(2) (heading)**

Repeal the heading, substitute:

*25% price reduction*

**28 After subsection 99ACE(2)**

Insert:

- (2A) If, on the day before the reduction day:
- (a) the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (b) if paragraph (a) does not apply—the original approved ex-manufacturer price of the related brand of the related item;
- has, by virtue of previous price reductions, been reduced by:
- (c) 15% or less, paragraph (3)(a) or (c), or (4)(a) or (c), as the case requires, applies; and
  - (d) more than 15% but less than 40%, paragraph (3)(b) or (d), or (4)(b) or (d), as the case requires, applies.

Note: If previous price reductions have been 40% or more, see subsection (1B).

- (2B) If, on the day before the reduction day:
- (a) the claimed price for a particular pack quantity of the related brand of the related item on 1 January 2016; or
  - (b) if paragraph (a) does not apply—the original claimed price for a particular pack quantity of the related brand of the related item;

has, by virtue of previous price reductions, been reduced by:

- (c) 15% or less, paragraph (4A)(a) applies; and
- (d) more than 15% but less than 40%, paragraph (4A)(b) applies.

Note: If previous price reductions have been 40% or more, see subsection (1B).

## **29 Paragraphs 99ACE(3)(a) and (b)**

Repeal the paragraphs, substitute:

- (a) in a price agreement, specify an agreed price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5), does not exceed the approved ex-manufacturer price for the related brand of the related item, on the day before the reduction day, reduced by 25%; or
- (b) in a price agreement, specify an agreed price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5A), does not exceed:
  - (i) 60% of the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—60% of the original approved ex-manufacturer price of the related brand of the related item; or
- (c) in a price determination, specify a determined price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5), does not exceed the approved ex-manufacturer price for the related brand of the related item, on the day before the reduction day, reduced by 25%; or
- (d) in a price determination, specify a determined price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5A), does not exceed:
  - (i) 60% of the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—60% of the original approved ex-manufacturer price of the related brand of the related item.

### **30 Paragraphs 99ACE(4)(a) and (b)**

Repeal the paragraphs, substitute:

- (a) in a price determination, specify a determined price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5), does not exceed the approved ex-manufacturer price for the related brand of the related item, on the day before the reduction day, reduced by 25%; or
- (b) in a price determination, specify a determined price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5A), does not exceed:
  - (i) 60% of the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—60% of the original approved ex-manufacturer price of the related brand of the related item; or
- (c) in a price agreement, specify an agreed price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5), does not exceed the approved ex-manufacturer price for the related brand of the related item, on the day before the reduction day, reduced by 25%; or
- (d) in a price agreement, specify an agreed price for the related brand of the related item that comes into force on the reduction day and, subject to subsections (4B) and (5A), does not exceed:
  - (i) 60% of the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—60% of the original approved ex-manufacturer price of the related brand of the related item.

### **31 Subsection 99ACE(4A)**

After “of the related brand of the related item that”, insert “comes into force on the reduction day and”.

### **32 Paragraphs 99ACE(4A)(a) and (b)**

Repeal the paragraphs, substitute:

- (a) subject to subsection (5D), does not exceed the claimed price for that pack quantity of the related brand of the related item, on the day before the reduction day, reduced by 25%; or
- (b) subject to subsection (5E), does not exceed:
  - (i) 60% of the claimed price for that pack quantity of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—60% of the original claimed price for that pack quantity of the related brand of the related item.

### **33 Subsection 99ACE(4B)**

Omit “subparagraphs (3)(a)(ii), (3)(b)(ii), (4)(a)(ii) and (4)(b)(ii)”, substitute “paragraphs (3)(a) to (d) and (4)(a) to (d)”.

### **34 Subsections 99ACE(5), (5A) and (5B)**

Repeal the subsections, substitute:

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

- (5) For the purposes of paragraph (3)(a) or (c) or (4)(a) or (c), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price mentioned in the relevant paragraph is to be worked out using a lower percentage (including zero %) specified in the determination.
- (5A) For the purposes of paragraph (3)(b) or (d) or (4)(b) or (d), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price mentioned in the relevant paragraph is to be worked out using a higher percentage specified in the determination.
- (5B) In making a determination under subsection (5) or (5A):
  - (a) the Minister must take into account what the approved ex-manufacturer 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 that the Minister considers relevant.
- (5C) If the Minister makes a determination under subsection (5) or (5A), the agreed price or determined price of the related brand of the related item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the relevant determination.
- (5D) For the purposes of paragraph (4A)(a), the Minister may, by written instrument, determine that the claimed price mentioned in that paragraph is to be worked out using a lower percentage (including zero %) specified in the determination.
- (5E) For the purposes of paragraph (4A)(b), the Minister may, by written instrument, determine that the claimed price mentioned in that paragraph is to be worked out using a higher percentage specified in the determination.
- (5F) In making a determination under subsection (5D) or (5E):
- (a) the Minister must take into account what the claimed price for the pack quantity 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 that the Minister considers relevant.
- (5G) If the Minister makes a determination under subsection (5D) or (5E), the claimed price for the pack quantity of the related brand of the related item is not to be further reduced under this section on any reduction day that occurs after the reduction day specified in the relevant determination.

### **35 Subsection 99ACF(1) (table item 1)**

Repeal the item.

### **36 After subsection 99ACF(2)**

Insert:

*Reduction by dollar amounts*

(2AA) Subject to section 99ACG, if:

- (a) section 99ACH applies to a listed brand (the *related brand*) of a pharmaceutical item (the *related item*) on a day specified in the section (the *reduction day*); and
- (b) on the day before the reduction day:
  - (i) the approved ex-manufacturer price of the related brand of the related item on 1 January 2016; or
  - (ii) if subparagraph (i) does not apply—the original approved ex-manufacturer price of the related brand of the related item; or
  - (iii) if applicable, one or more claimed prices of the related brand of the related item on 1 January 2016; or
  - (iv) if subparagraph (iii) does not apply—if applicable, one or more claimed prices, of the related brand of the related item;  
have, by virtue of previous price reductions, been reduced by:
    - (v) 15% or less, subsection (2AB) applies; and
    - (vi) more than 15% but less than 40%, subsection (2AC) applies.

(2AB) Subject to subsections (2A) and (3AA), the approved ex-manufacturer price, or (if applicable) each claimed price, for the related brand of the related item that comes into force on the reduction day must not exceed the approved ex-manufacturer price, or each of the claimed prices, of the related brand of the related item, on the day before the reduction day, reduced by 25%.

(2AC) Subject to subsections (2A) and (3AB), the approved ex-manufacturer price, or (if applicable) each claimed price, for the related brand of the related item that comes into force on the reduction day must not exceed:

- (a) 60% of the approved ex-manufacturer price, or each of the claimed prices, of the related brand of the related item on 1 January 2016; or
  - (b) if paragraph (a) does not apply—60% of the original approved ex-manufacturer price, or each of the claimed prices, of the related brand of the related item.
-

**37 Subsection 99ACF(2A)**

Omit “subsection (1) and paragraph (2)(b)”, substitute “subsection (1), paragraph (2)(b) and subsections (2AB) and (2AC)”.

**38 After subsection 99ACF(3)**

Insert:

(3AA) For the purposes of subsection (2AB), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price, or (if applicable) each claimed price, mentioned in that subsection (the *specified provision*) is to be worked out using a lower percentage (including zero %) specified in the determination.

(3AB) For the purposes of paragraphs (2AC)(a) and (b), the Minister may, by written instrument, determine that the relevant approved ex-manufacturer price, or (if applicable) each claimed price, mentioned in those paragraphs (the *specified provision*) is to be worked out using a higher percentage specified in the determination.

**39 Subsection 99ACF(3A)**

Omit “the application of item 2, 3, 4, 5, or 6 of the table in subsection (1)”, substitute “the application of an item of the table in subsection (1), or subsection (2AB) or paragraphs (2AC)(a) and (b)”.

**40 At the end of subsection 99ACF(3B)**

Add “, (3AA) or (3AB)”.

**41 Subparagraph 99ACG(b)(iii)**

Omit “item 1 of the table in section 99ACF”, substitute “section 99ACH”.

**42 At the end of paragraph 99ACG(b)**

Add:

(iv) subsection 99ACF(2AB) or (2AC);

**43 Section 99ACH (heading)**

Repeal the heading, substitute:

**99ACH 25% statutory price reduction flow-on to related brands**

**44 Paragraph 99ACH(1)(a)**

Omit “section 99ACB”, substitute “subsection 99ACB(5) or (5A)”.

**45 After subsection 99ACH(1)**

Insert:

(1A) If:

- (a) paragraph 99ACB(2)(d) applies in relation to a listed brand of the existing item; and
- (b) on or after the day that paragraph 99ACB(2)(d) applies, a price agreement or a determination under section 85B is in force in relation to any of the listed brands (the *related brand*) of a pharmaceutical item (the *related item*) mentioned in subsection (2); and
- (c) the related item is not a combination item; and
- (d) the related item is not an exempt item;

then this section applies to the related brand of the related item as if:

- (e) section 99ACB had applied to the brand of the pharmaceutical item; and
- (f) the current price remains the agreed price for the brand (the *new brand*) of the pharmaceutical item (the *new item*); and
- (g) the agreed price comes into force on the day that paragraph 99ACB(2)(d) is satisfied (the *reduction day*).

**46 Subsection 99ACH(2)**

Omit “paragraph (1)(c)”, substitute “paragraphs (1)(c) and (1A)(b)”.

**47 Paragraph 99ACHA(1)(c)**

Omit “item 1 in the table in section 99ACF”, substitute “section 99ACH”.



## **Part 2—16% price reduction**

### *National Health Act 1953*

#### **48 Section 99AC**

Omit “25% price reduction” (wherever occurring), substitute “16% price reduction”.

#### **49 Subsections 99ACA(2), (2A) and (2B)**

Repeal the subsections, substitute:

- (2) A listed component drug contained in a drug in a combination item has been subject to a **12.5% price reduction** if:
  - (a) any of the following has applied before 1 February 2011 to a brand of a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination item:
    - (i) section 99ACB;
    - (ii) subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF; or
  - (b) a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination item is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied.
- (2A) A listed component drug contained in a drug in a combination item has been subject to a **16% price reduction** if:
  - (a) any of the following has applied to a brand of a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination item:
    - (i) section 99ACB;
    - (ii) subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF; or
  - (b) a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination

item is in a class of pharmaceutical items to which a 16% administrative price reduction has applied.

(2B) A listed component drug contained in a drug in a combination item has been subject to a **25% price reduction** if:

- (a) any of the following has applied on or after 1 October 2018 and before 1 July 2022 to a brand of a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination item:
  - (i) section 99ACB;
  - (ii) subsection 99ACF(2AB) or (2AC); or
- (b) a pharmaceutical item that has the listed component drug and has the same manner of administration as the combination item is in a class of pharmaceutical items to which a 25% administrative price reduction has applied.

To avoid doubt, a 25% price reduction occurs even if the reduction is in fact more or less than 25% (including zero %).

Note: Subparagraph (a)(ii)—subsections 99ACF(2AB) and (2AC) were repealed by Part 2 of Schedule 1 to the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018*.

## **50 Subdivision B of Division 3A of Part VII (heading)**

Repeal the heading, substitute:

### **Subdivision B—16% price reductions for new brands of pharmaceutical items that are not combination items**

## **51 Section 99ACB (heading)**

Repeal the heading, substitute:

### **99ACB 16% price reduction for new brands of pharmaceutical items that are not combination items**

## **52 Paragraph 99ACB(2)(c)**

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

## **53 Paragraph 99ACB(2)(d)**

Repeal the paragraph.

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**54 Subparagraph 99ACB(3)(a)(ii)**

Omit “section 99ACH”, substitute “item 1 of the table in section 99ACF”.

**55 Subparagraph 99ACB(3)(a)(iii)**

Repeal the subparagraph.

**56 Subsection 99ACB(4) (heading)**

Repeal the heading, substitute:

*16% price reduction*

**57 Subsections 99ACB(4A), (5) and (5A)**

Repeal the subsections, substitute:

- (5) Subject to subsection (6), the agreed price for 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 16%.

**58 Subsection 99ACB(6)**

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

**59 Subsections 99ACB(6A) to (6D)**

Repeal the subsections.

**60 Paragraph 99ACC(6)(a)**

Omit “subsection 99ACF(1), (2), (2AB) or (2AC) because of section 99ACH”, substitute “subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF”.

**61 Section 99ACD (heading)**

Repeal the heading, substitute:

**99ACD 16% price reduction for new brands of combination items**

**62 Paragraph 99ACD(1A)(c)**

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

**63 Paragraph 99ACD(1A)(d)**

Repeal the paragraph.

**64 Subsection 99ACD(4) (heading)**

Repeal the heading, substitute:

*16% price reduction*

**65 Subsections 99ACD(4A), (5) and (5A)**

Repeal the subsections, substitute:

- (5) Subject to subsections (6) to (7), the agreed price of the new brand of the trigger combination item 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 16%.

*Adjustment for prior price reductions to component drugs*

- (6) If, on a day before the determination day:
- (a) one or more of the listed component drugs (the **component**) contained in the drug in the existing item had been subject to one of the following (the **prior price reduction of the component**):
    - (i) a 12.5% price reduction;
    - (ii) a 16% price reduction;
    - (iii) a 25% price reduction; and
  - (b) because of the prior price reduction of the component, the approved ex-manufacturer price of the existing brand of the existing item was, or if subparagraph (a)(iii) applies, was or would have been, reduced;
- then the reduction referred to in subsection (5) is to be adjusted to reflect:
- (c) the percentage (the **flowed-on percentage**) of the prior price reduction of the component that was taken into account in

working out the amount of the reduction to the approved ex-manufacturer price of the existing brand of the existing item; and

(d) the quantity of the component contained in the drug in the existing item.

(6A) For the purposes of subsection (6), if:

(a) the prior price reduction of the component was a 12.5% price reduction; and

(b) the flowed-on percentage was 100%;

then the reduction referred to in subsection (5) is to be adjusted so that there is no further reduction in relation to the component.

(6B) For the purposes of subsection (6), if:

(a) the prior price reduction of the component was a 12.5% price reduction; and

(b) the flowed-on percentage was less than 100%;

then the reduction referred to in subsection (5) is to be adjusted so that the percentage worked out as follows is taken into account in relation to the component:

$$12.5\% - (\text{Flowed-on percentage} \times 12.5\%)$$

#### **66 Subsection 99ACD(7)**

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

#### **67 Subsections 99ACD(7A) to (7D)**

Repeal the subsections.

#### **68 Section 99ACE (heading)**

Repeal the heading, substitute:

#### **99ACE Flow-on of 16% price reduction to related brands of combination items**

#### **69 Subsections 99ACE(1A) and (1B)**

Repeal the subsections.

**70 Subsection 99ACE(2) (heading)**

Repeal the heading, substitute:

*16% price reduction*

**71 Subsections 99ACE(2A) and (2B)**

Repeal the subsections.

**72 Paragraphs 99ACE(3)(a) to (d)**

Repeal the paragraphs, substitute:

- (a) in a price agreement, specify an agreed price for the related brand of the related item that:
  - (i) comes into force on the reduction day; and
  - (ii) subject to subsections (4B) and (5) to (5B), does not exceed the approved ex-manufacturer price in force, on the day before that day, for the related brand of the related item, reduced by 16%; or
- (b) in a price determination, specify a determined price for the related brand of the related item that:
  - (i) comes into force on the reduction day; and
  - (ii) subject to subsections (4B) and (5) to (5B), does not exceed the approved ex-manufacturer price in force, on the day before that day, for the related brand of the related item, reduced by 16%.

**73 Paragraphs 99ACE(4)(a) to (d)**

Repeal the paragraphs, substitute:

- (a) in a price determination, specify a determined price for the related brand of the related item that:
  - (i) comes into force on the reduction day; and
  - (ii) subject to subsections (4B) and (5) to (5B), does not exceed the approved ex-manufacturer price in force, on the day before that day, for the related brand of the related item, reduced by 16%; or
- (b) in a price agreement, specify an agreed price for the related brand of the related item that:
  - (i) comes into force on the reduction day; and

- (ii) subject to subsections (4B) and (5) to (5B), does not exceed the approved ex-manufacturer price in force, on the day before that day, for the related brand of the related item, reduced by 16%.

#### **74 Subsection 99ACE(4A)**

Repeal the subsection, substitute:

- (4A) If a determination under subsection 85B(3) was in force for a particular pack quantity of the related brand of the related item on the day before the reduction day, the Minister may, in a determination under subsection 85B(3), specify a claimed price for that pack quantity of the related brand of the related item that:
  - (a) comes into force on the reduction day; and
  - (b) subject to subsections (5) to (5B), does not exceed the claimed price in force for that pack quantity of the related brand of the related item on the day before that day, reduced by 16%.

#### **75 Subsection 99ACE(4B)**

Omit “paragraphs (3)(a) to (d) and (4)(a) to (d)”, substitute “subparagraphs (3)(a)(ii), (3)(b)(ii), (4)(a)(ii) and (4)(b)(ii)”.

#### **76 Subsections 99ACE(5) to (5G)**

Repeal the subsections, substitute:

*Adjustment for prior price reductions to component drugs*

- (5) If, on a day before the reduction day:
  - (a) one or more of the listed component drugs (the **component**) contained in the related item had been subject to one of the following (the **prior price reduction of the component**):
    - (i) a 12.5% price reduction;
    - (ii) a 16% price reduction;
    - (iii) a 25% price reduction; and
  - (b) because of the prior price reduction of the component, the approved ex-manufacturer price of the related brand of the related item was, or if subparagraph (a)(iii) applies, was or would have been, reduced;

then the reduction referred to in subsection (3), (4) or (4A) is to be adjusted to reflect:

- (c) the percentage (the *flowed-on percentage*) of the prior price reduction of the component that was taken into account in working out the amount of the reduction to the approved ex-manufacturer price of the related brand of the related item; and
- (d) the quantity of the component contained in the drug in the related item.

(5A) For the purposes of subsection (5), if:

- (a) the prior price reduction of the component was a 12.5% price reduction; and
- (b) the flowed-on percentage was 100%;

then the reduction referred to in subsection (3), (4) or (4A) is to be adjusted so that there is no further reduction in relation to the component.

(5B) For the purposes of subsection (5), if:

- (a) the prior price reduction of the component was a 12.5% price reduction; and
- (b) the flowed-on percentage was less than 100%;

then the reduction referred to in subsection (3), (4) or (4A) is to be adjusted so that the percentage worked out as follows is taken into account in relation to the component:

$$12.5\% - (\text{Flowed-on percentage} \times 12.5\%)$$

## **77 Subsection 99ACF(1) (before table item 2)**

Insert:

1      99ACH      16%

## **78 Subsections 99ACF(2AA), (2AB) and (2AC)**

Repeal the subsections.

## **79 Subsection 99ACF(2A)**

Omit “subsection (1), paragraph (2)(b) and subsections (2AB) and (2AC)”, substitute “subsection (1) and paragraph (2)(b)”.

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**80 Subsections 99ACF(3AA) and (3AB)**

Repeal the subsections.

**81 Subparagraph 99ACG(b)(iii)**

Omit “section 99ACH”, substitute “item 1 of the table in section 99ACF”.

**82 Subparagraph 99ACG(b)(iv)**

Repeal the subparagraph.

**83 Section 99ACH (heading)**

Repeal the heading, substitute:

**99ACH 16% statutory price reduction flow-on to related brands**

**84 Paragraph 99ACH(1)(a)**

Omit “subsection 99ACB(5) or (5A)”, substitute “section 99ACB”.

**85 Subsection 99ACH(1A)**

Repeal the subsection.

**86 Subsection 99ACH(2)**

Omit “paragraphs (1)(c) and (1A)(b)”, substitute “paragraph (1)(c)”.

**87 Paragraph 99ACHA(1)(c)**

Omit “section 99ACH”, substitute “item 1 in the table in section 99ACF”.

## Schedule 2—Statutory price reductions

### Part 1—Amendments commencing day after Royal Assent

#### *National Health Act 1953*

##### **1 Section 99AC**

Omit:

- (b) arise if a pharmaceutical item has had a drug on F1 for 5 years on a particular day.

substitute:

- (b) occur on a particular day if, on that day, the pharmaceutical item has a drug on F1 and that drug has been a listed drug for at least 5 years, 10 years or 15 years.

Price reductions for listed brands of pharmaceutical items under this Division are subject to:

- (a) determinations made by the Minister to not apply, or reduce, the price reduction; or
- (b) price reductions made under Subdivision E of Division 3B (see section 99ACG).

##### **2 Subsection 99ACF(1) (heading)**

Repeal the heading, substitute:

*Reduction equal to percentage etc.*

##### **3 Paragraph 99ACF(1)(a)**

After “section” (wherever occurring), insert “or subsection”.

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**4 Subsection 99ACF(1)**

Omit “subsection (2A)”, substitute “subsections (2A) and (3)”.

**5 Subsection 99ACF(1)**

Omit “by the percentage specified in column 3 of the table for the section”, substitute “by the percentage or method specified in column 3 of the table for the section or subsection”.

**6 Subsection 99ACF(1) (table, heading to column headed “Section”)**

Repeal the heading, substitute:

**Section or subsection**

**7 Subsection 99ACF(1) (table, heading to column headed “Percentage”)**

Repeal the heading, substitute:

**Percentage or method**

**8 Subsection 99ACF(1) (at the end of the table)**

Add:

3	99ACJ	10%
4	99ACK	5%
5	99ACL(1)	10%
6	99ACL(2)	(a) first, 10%; and (b) second, using the price worked out under paragraph (a), by 5%

**9 Paragraph 99ACF(2)(a)**

After “section”, insert “or subsection”.

**10 Paragraphs 99ACF(2)(b) and (c)**

Omit “the percentage specified in column 3 of the table for the section”, substitute “the percentage or method specified in column 3 of the table for the section or subsection”.

## 11 Before subsection 99ACF(4)

Insert:

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

- (3) In relation to a listed brand of a pharmaceutical item, the Minister may, by written instrument, determine that:
- (a) the approved ex-manufacturer price is, or (if applicable) one or more claimed prices are, not to be reduced under a provision mentioned in items 2 to 6 of the table in subsection (1) (the *specified provision*) in relation to a particular reduction day; or
  - (b) the approved ex-manufacturer price is, or (if applicable) one or more of the claimed prices are, to be reduced by a lower percentage than would otherwise apply under a provision mentioned in items 2 to 6 of the table in subsection (1) (the *specified provision*) in relation to a particular reduction day.
- (3A) In making a determination in relation to the application of item 2, 3, 4, 5, or 6 of the table in subsection (1):
- (a) the Minister must take into account what the approved ex-manufacturer price, and (if applicable) each of the claimed prices, of the listed brand of the pharmaceutical 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 that the Minister considers relevant.
- (3B) If the Minister makes a determination in relation to a specified provision, the approved ex-manufacturer price is, and (if applicable) each of the claimed prices are, not to be further reduced under that specified provision on any reduction day that occurs after the reduction day specified in the determination made under subsection (3).

## 12 Subsection 99ACF(4)

Omit “after the reduction day”, substitute “on or after the reduction day”.

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**13 Paragraph 99ACG(b)**

Omit “this subsection”, substitute “this section”.

**14 Section 99ACHA (heading)**

Repeal the heading, substitute:

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

**15 Paragraph 99ACHA(1)(b)**

Repeal the paragraph, substitute:

- (b) the 5% price reduction day is on or after the fifth anniversary of the drug being a listed drug; and

**16 Paragraph 99ACHA(1)(c)**

Omit “this Subdivision”, substitute “subsection 99ACF(1) or (2) because of item 1 in the table in section 99ACF”.

**17 At the end of subsection 99ACHA(2)**

Add:

- ; (f) 1 April 2021;
- (g) 1 April 2022.

**18 At the end of Division 3A of Part VII**

Add:

**99ACJ 10% statutory price reduction for drugs on F1—tenth anniversary**

- (1) This section applies to a brand of a pharmaceutical item on a 10% price reduction day if:
  - (a) the drug in the pharmaceutical item is on F1 on the 10% price reduction day; and
  - (b) the 10% 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 a brand of a pharmaceutical item that has the drug, on the day before the

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10% price reduction day, has not been reduced under subsection 99ACF(1) or (2) because of:

- (i) item 3 in the table in section 99ACF on a previous 10% price reduction day; or
  - (ii) item 5 in the table in section 99ACF on 1 June 2018.
- (2) In this section, each of the following is a **10% price reduction day**:
- (a) 1 April 2019;
  - (b) 1 April 2020;
  - (c) 1 April 2021.

**99ACK 5% statutory price reduction for drugs on F1—15th 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 15th anniversary of the drug being a listed drug; and
  - (c) the approved ex-manufacturer price of a brand of a pharmaceutical item that has the drug, on the day before the 5% price reduction day, has not been reduced under subsection 99ACF(1) or (2) because of:
    - (i) item 4 in the table in section 99ACF on a previous 5% price reduction day; or
    - (ii) item 6 in the table in section 99ACF on 1 June 2018.
- (2) In this section, each of the following is a **5% price reduction day**:
- (a) 1 April 2019;
  - (b) 1 April 2020;
  - (c) 1 April 2021.

**99ACL Special rule—statutory price reduction for drugs on F1**

*Tenth anniversary of listing of drug falls on or before 1 June 2018*

- (1) This subsection applies to a brand of a pharmaceutical item if:
-

- (a) the drug in the pharmaceutical item is on F1 on 1 June 2018 (the **price reduction day**); and
- (b) the price reduction day is on or after the tenth anniversary of the drug being a listed drug; and
- (c) subsection (2) is not satisfied in relation to the brand of the pharmaceutical item.

*15th anniversary of listing of drug falls on or before 1 June 2018*

- (2) This subsection applies to a brand of a pharmaceutical item if:
  - (a) the drug in the pharmaceutical item is on F1 on 1 June 2018 (the **price reduction day**); and
  - (b) the price reduction day is on or after the 15th anniversary of the drug being a listed drug.

## Part 2—Amendments commencing 1 July 2022

### *National Health Act 1953*

#### **19 Section 99AC**

Omit:

Price reductions for listed brands of pharmaceutical items under this Division are subject to:

- (a) determinations made by the Minister to not apply, or reduce, the price reduction; or
- (b) price reductions made under Subdivision E of Division 3B (see section 99ACG).

substitute:

Price reductions for listed brands of pharmaceutical items under this Division are subject to price reductions made under Subdivision E of Division 3B (see section 99ACG).

#### **20 Subsections 99ACF(3) to (3B)**

Repeal the subsections.



## **Schedule 3—Price disclosure price reduction thresholds**

### **Part 1—Amendments commencing day after Royal Assent**

#### *National Health Act 1953*

##### **1 Subsection 99ADB(1)**

Insert:

*data collection period*, for a brand of a pharmaceutical item, has the meaning given by section 99ADBA.

*related brand*, of a brand of a pharmaceutical item, means a brand of a pharmaceutical item that has the same drug and manner of administration as the first-mentioned pharmaceutical item (including another brand of the same pharmaceutical item), but does not include a brand of an exempt item.

*start day*, for a brand of a pharmaceutical item, means the day that the brand was first required to comply with the price disclosure requirements under section 99ADD.

##### **2 At the end of Subdivision A of Division 3B of Part VII**

Add:

##### **99ADBA Meaning of data collection period**

*Start of first data collection period*

- (1) The first *data collection period* for a brand of a pharmaceutical item starts on the brand's start day.

*End of first data collection period*

- (2) If, on the day before the brand's start day (the *starting brand*) the price disclosure requirements apply to a related brand of the

**Schedule 3** Price disclosure price reduction thresholds  
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starting brand, the starting brand's first data collection period ends when the *data collection period* for any of the related brands ends.

- (3) Otherwise, the starting brand's first *data collection period* ends on:
- (a) if the start day occurs between 2 April and 1 October—the next 31 March; or
  - (b) if the start day occurs between 2 October and 1 April—the next 30 September.

*Start and end of subsequent data collection periods*

- (4) After the first *data collection period* for a listed brand of a pharmaceutical item, each subsequent data collection period for the brand:
- (a) starts immediately after the end of the previous data collection period; and
  - (b) ends on the next 31 March or 30 September, whichever is sooner.

Example 1: If a brand to which subsection (2) applies has a start day of 1 July 2016, and the data collection period for a related brand ends on 30 September 2016:

- (a) the first data collection period starts on 1 July 2016; and
- (b) the first data collection period ends on 30 September 2016; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2016, 1 April 2017, 1 October 2017 and so on.

Example 2: If a brand to which subsection (3) applies has a start day of 1 August 2016:

- (a) the first data collection period starts on 1 August 2016; and
- (b) the first data collection period ends on 31 March 2017; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 April 2017, 1 October 2017, 1 April 2018 and so on.

Example 3: If a brand to which subsection (3) applies has a start day of 1 December 2016:

- (a) the first data collection period starts on 1 December 2016; and
- (b) the first data collection period ends on 30 September 2017; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2017, 1 April 2018, 1 October 2018 and so on.

### **3 Paragraph 99ADH(1)(a)**

After “pharmaceutical item”, insert “(the *WADP brand*) in respect of a data collection period for the brand”.

### **4 Paragraph 99ADH(1)(c)**

Repeal the paragraph, substitute:

- (c) the unadjusted price reduction for the brand of the pharmaceutical item is:
  - (i) if the drug and manner of administration of the pharmaceutical item has been on F2 for less than 42 months—at least 10%; and
  - (ii) subject to subparagraph (iii), if the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months—at least 30%; and
  - (iii) if the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months and has had 2 consecutive price reductions under subparagraph (ii) in relation to the brand of the pharmaceutical item—at least 10%.

### **5 After subsection 99ADH(2)**

Insert:

- (2A) For the purposes of paragraph (1)(c), 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 *WADP brand* 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 *WADP brand* that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the *WADP brand*; or
    - (ii) there were 2 or more related brands of the *WADP brand* that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.

**6 Subsection 99ADH(5)**

Omit “after the reduction day”, substitute “on or after the reduction day”.

**7 Application**

The amendments made by this Part apply to a determination of a day (the *reduction day*) by the Minister, by legislative instrument, for the purposes of section 99ADH of the *National Health Act 1953* if the reduction day occurs on or after the day this item commences.

## **Part 2—Amendments commencing 1 July 2022**

### *National Health Act 1953*

#### **8 Subsection 99ADB(1)**

Repeal the following definitions:

- (a) definition of *data collection period*;
- (b) definition of *related brand*;
- (c) definition of *start day*.

#### **9 Section 99ADBA**

Repeal the section.

#### **10 Paragraph 99ADH(1)(a)**

Omit “(the *WADP brand*) in respect of a data collection period for the brand”.

#### **11 Paragraph 99ADH(1)(c)**

Repeal the paragraph, substitute:

- (c) the unadjusted price reduction for the brand of the pharmaceutical item is at least 10%.

#### **12 Subsection 99ADH(2A)**

Repeal the subsection.

## Schedule 4—New brands

### Part 1—Amendments commencing day after Royal Assent

#### *National Health Act 1953*

##### **1 After subsection 85AB(4)**

Insert:

- (4A) For the purposes of working out whether paragraph (4)(a) or (b) is satisfied, a brand of a pharmaceutical item that has the drug is to be disregarded if:
- (a) both:
    - (i) subsection 99ACB(3A) or (3B) applies to the brand of the pharmaceutical item that has the drug; and
    - (ii) there is not another brand of the pharmaceutical item that has the drug that is a listed brand; or
  - (b) both:
    - (i) subsection 99ACB(3A) or (3B) applies to the brand of the pharmaceutical item that has the drug; and
    - (ii) the drug is not on F2; or
  - (c) both:
    - (i) subsection 99ACB(3B) applies to the brand of the pharmaceutical item that has the drug; and
    - (ii) the tenth anniversary of the drug in the pharmaceutical item being on F1 has not occurred.

##### **2 Subsection 99ACB(1)**

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

##### **3 After subsection 99ACB(3)**

Insert:

- (3A) This section does not apply in relation to the new brand of the trigger item if:
-

- (a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (b) the determination day in relation to the new brand of the trigger item is on or before the fifth anniversary of the drug in the pharmaceutical item being on F1; and
  - (c) the responsible person for the new brand of the trigger item is the same person as the responsible person for the existing listed brand of the pharmaceutical item; and
  - (d) either of the following apply:
    - (i) there is not another brand of the pharmaceutical item that has the drug that is a listed brand;
    - (ii) the drug is not on F2.
- (3B) This section does not apply in relation to the new brand of the trigger item if:
- (a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (b) the Minister has made a determination under section 99ACBA in relation to the new brand of the trigger item; and
  - (c) the determination under section 99ACBA has not ceased to have effect.

#### **4 At the end of Subdivision B of Division 3A of Part VII**

Add:

#### **99ACBA Ministerial determination—brand of pharmaceutical item that is not a combination item is not a new brand**

- (1) If:
- (a) a brand of a pharmaceutical item (the *trigger item*) is not a combination item; and
  - (b) the brand of the trigger item:
    - (i) is not a listed brand of the trigger item; and
    - (ii) is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (c) the Minister is satisfied that the determination day in relation to the brand of the trigger item is to be after the fifth

**Schedule 4** New brands

**Part 1** Amendments commencing day after Royal Assent

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anniversary, and before the tenth anniversary, of the drug in the pharmaceutical item being on F1;  
the Minister may determine, by notifiable instrument, that the brand of the trigger item is not a new brand for the purposes of section 99ACB.

- (2) If the Minister makes a determination under this section in relation to the brand of the trigger item, it must be made before the determination day in relation to the brand of the trigger item.
- (3) In making a determination, the Minister may have regard to:
  - (a) any advice given by the Pharmaceutical Benefits Advisory Committee; and
  - (b) any information provided by the responsible person for the brand of the trigger item; and
  - (c) any other matter that the Minister considers relevant.
- (4) A determination made under this section ceases to have effect on whichever is the earliest of the following:
  - (a) the day that another brand of the pharmaceutical item becomes a listed brand;
  - (b) the day that the drug in the pharmaceutical item does not satisfy all of the criteria for F1;
  - (c) the tenth anniversary of the drug in the pharmaceutical item being on F1.
- (5) In this section:

*determination day* has the same meaning as in paragraph 99ACB(1)(a).

**5 Subsection 99ACD(1)**

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

**6 After subsection 99ACD(2)**

Insert:

- (3) This section does not apply in relation to the new brand of the trigger combination item if:
    - (a) all of the following apply:
-



- (i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
- (ii) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item;
- (iii) the determination day in relation to the new brand of the trigger combination item is on or before the fifth anniversary of the declaration under subsection 85(2) being made;
- (iv) the responsible person for the new brand of the trigger combination item is the same as the responsible person for the existing listed brand of the pharmaceutical item;
- (v) the drug is not on F2; or
- (b) all of the following apply:
  - (i) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item;
  - (ii) the Minister has made a determination under section 99ACEA in relation to the new brand of the trigger combination item;
  - (iii) the determination under section 99ACEA has not ceased to have effect.

## **7 At the end of Subdivision C of Division 3A of Part VII**

Add:

### **99ACEA Ministerial determination—brand of pharmaceutical item that is a combination item is not a new brand**

- (1) If:
  - (a) a brand of a pharmaceutical item (the *trigger combination item*) is a combination item; and
  - (b) the brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (c) a declaration under subsection 85(2) is in force in relation to the drug in the pharmaceutical item; and

- (d) the Minister is satisfied that the determination day in relation to the brand of the trigger combination item is after the fifth anniversary, and before the tenth anniversary, of the declaration under subsection 85(2) being made;
- the Minister may determine, by notifiable instrument, that the brand of the trigger combination item is not a new brand for the purposes of section 99ACD.
- (2) If the Minister makes a determination under this section in relation to the brand of the trigger combination item, it must be made before the determination day in relation to the brand of the trigger combination item.
- (3) In making a determination, the Minister may have regard to:
- (a) any advice given by the Pharmaceutical Benefits Advisory Committee; and
  - (b) any information provided by the responsible person for the brand of the trigger combination item; and
  - (c) any other matter that the Minister considers relevant.
- (4) A determination made under this section ceases to have effect on whichever is the earliest of the following:
- (a) the tenth anniversary of the declaration under subsection 85(2) being made;
  - (b) the day that the drug is on F2.
- (5) In this section:
- determination day* has the same meaning as in paragraph 99ACD(1)(a).

## 8 After subsection 101(4AC)

Insert:

*Functions relating to determinations that brands are not new brands*

- (4AD) The Pharmaceutical Benefits Advisory Committee may give advice to the Minister in relation to whether the Minister should determine that a brand of a pharmaceutical item is not a new brand for the purposes of section 99ACB or 99ACD.
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## **Part 2—Amendments commencing 1 July 2022**

### *National Health Act 1953*

#### **9 Subsection 85AB(4A)**

Repeal the subsection, substitute:

- (4A) For the purposes of working out whether subsection (4) is satisfied, a brand of a pharmaceutical item that has the drug is to be disregarded if:
- (a) before 1 July 2022, subsection 99ACB(3A) or (3B), as in force before its repeal by the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018*, applied in relation to the brand of the pharmaceutical item; and
  - (b) all of the following apply:
    - (i) another brand of the pharmaceutical item has not become a listed brand;
    - (ii) the drug is not on F2;
    - (iii) the tenth anniversary of the drug in the pharmaceutical item being on F1 has not occurred.

#### **10 Subsection 99ACB(1)**

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

#### **11 Subsections 99ACB(3A) and (3B)**

Repeal the subsections, substitute:

- (3A) This section does not apply in relation to the new brand of the trigger item if:
- (a) the new brand of the trigger item is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (b) before 1 July 2022, subsection 99ACB(3A) or (3B), as in force before its repeal by the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018*, applied in relation to the new brand of the trigger item; and

- (c) all of the following apply:
  - (i) the drug is not on F2;
  - (ii) the tenth anniversary of the drug in the pharmaceutical item being on F1 has not occurred;
  - (iii) another brand of the pharmaceutical item has not become a listed brand.

## 12 Section 99ACBA

Repeal the section.

## 13 Subsection 99ACD(3)

Repeal the subsection, substitute:

- (3) This section does not apply in relation to the new brand of the trigger combination item if:
  - (a) the new brand of the trigger combination item is a new presentation of an existing listed brand of a pharmaceutical item; and
  - (b) before 1 July 2022, paragraph 99ACD(3)(a) or (b), as in force before its repeal by the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2018*, applied in relation to the new brand of the trigger combination item; and
  - (c) both of the following apply:
    - (i) the tenth anniversary of the declaration under subsection 85(2) relating to the drug in the pharmaceutical item being made has not occurred;
    - (ii) the drug is not on F2.

## 14 Section 99ACEA

Repeal the section.

## 15 Subsection 101(4AD)

Repeal the subsection.

## **Schedule 5—Pharmacy location rules**

### **Part 1—Australian Community Pharmacy Authority**

#### *National Health Act 1953*

##### **1 Subsection 90(3C)**

Repeal the subsection.

##### **2 Section 99Y**

Repeal the section.

## **Part 2—Miscellaneous**

### *National Health Act 1953*

#### **3 Subsection 84(1) (definition of *subject to an outstanding staged reduction*)**

Repeal the definition.

#### **4 Subsections 99ACE(5), (5A) and (5B)**

Omit “or (4)”, substitute “, (4) or (4A)”.

## **Schedule 6—Name changes**

### *National Health Act 1953*

#### **1 At the end of section 85**

Add:

*Alternative names or terminology*

- (11) The Minister may, by notifiable instrument, determine that, for the purposes of this Part:
- (a) more than one name is recognised for the same listed drug; or
  - (b) more than one description is recognised for the same form of a listed drug; or
  - (c) more than one description is recognised for the same manner of administration of a form of a listed drug.
- (12) Without limiting subsection (11), the Minister may determine a name or description as being used during a period of time, such as before or after a specified date.

## Schedule 7—Safety net

### *National Health Act 1953*

#### **1 Subsection 84(1)**

Insert:

*value for safety net purposes* means:

- (a) for the supply of a pharmaceutical benefit—the amount prescribed by regulations made for the purposes of subsection 84C(1E); and
- (b) for the supply of a repatriation benefit—the amount charged for the supply; and
- (c) for the supply of out-patient medication—the applicable amount in relation to the supply.

#### **2 Subsection 84AAA(1)**

Omit “(whether or not that supply is a supply of a kind described in paragraph 84C(4A)(a))”.

#### **3 At the end of subparagraph 84AAA(1)(b)(iii)**

Add “and”.

#### **4 Paragraph 84AAA(1)(b)**

Omit “whether or not the supply was a supply of the kind described in paragraph 84C(4A)(a); and”.

#### **5 At the end of section 84AAA**

Add:

- (4) In this section, a reference to a pharmaceutical benefit includes a reference to a repatriation pharmaceutical benefit.

#### **6 Subsections 84C(1AA) and (1C)**

Repeal the subsections, substitute:

- (1AA) A person who has been, at any time during a relevant entitlement period, a general patient is eligible to be issued with a concession



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card in respect of that period if the total value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made:

- (a) to the person during the period; or
  - (b) to the person and the person's family during the period;
- is not less than the amount of the general patient safety net (within the meaning of section 99F).

Note: Supplies of pharmaceutical benefits may include supplies referred to in subsections 99(2A), (2AB) and (2B).

- (1B) A person is eligible to be issued with a concession card at the time of the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication to the person or a member of the person's family, if including the value for safety net purposes of the supply in the total mentioned in subsection (1AA) would fulfil that subsection.
- (1C) A person who has been, at any time during a relevant entitlement period, a concessional beneficiary is eligible to be issued with an entitlement card in respect of that period if either of the following paragraphs applies:
  - (a) the total of:
    - (i) the value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person during the relevant entitlement period when the person was a concessional beneficiary; and
    - (ii) where the person has, during the relevant entitlement period, been a general patient—the transferred value of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person during the period when the person was a general patient;is not less than the amount of the concessional beneficiary safety net (within the meaning of section 99F);
  - (b) the total of:
    - (i) the value for safety net purposes of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person and the person's family during the relevant entitlement

period when the person was a concessional beneficiary;  
and

- (ii) where the person has, during the relevant entitlement period, been a general patient—the transferred value of supplies of pharmaceutical benefits, repatriation pharmaceutical benefits and out-patient medication made to the person and the person’s family during the period when the person was a general patient;
- is not less than the amount of the concessional beneficiary safety net (within the meaning of section 99F).

Note: Supplies of pharmaceutical benefits may include supplies referred to in subsections 99(2A), (2AB) and (2B).

- (1D) A person is eligible to be issued with an entitlement card at the time of the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication to the person or a member of the person’s family if:
  - (a) where the person is a concessional beneficiary at the time of the supply—including the value for safety net purposes of the supply; or
  - (b) where the person is a general patient at the time of the supply—including the transferred value of the supply;in the total mentioned in paragraph (1C)(a) or (b) would fulfil that paragraph.
- (1E) The regulations may prescribe the value for safety net purposes of a supply of a pharmaceutical benefit.
- (1F) Regulations made for the purposes of subsection (1E) must take into account the amount charged for the supply, but may make adjustments to the value for safety net purposes such as:
  - (a) excluding certain components of the amount charged; or
  - (b) setting a maximum limit on the value.

## **7 At the end of subparagraph 84C(4)(a)(ii)**

Add “and”.

## **8 Paragraph 84C(4)(b)**

Omit all the words after “supply,”, substitute “the person is not a holder of an entitlement card; and”.

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**9 Paragraphs 84C(4)(c) to (e)**

Repeal the paragraphs, substitute:

- (c) in a case where the supply is made upon a general benefit prescription and the Commonwealth price for the pharmaceutical benefit exceeds \$28.60—the amount received in respect of the supply is equal to the sum of the following:
  - (i) \$28.60 (less any allowable discount);
  - (ii) if an amount may be charged for the supply under subsection 87(2A)—that amount;
  - (iii) any charge for supply at a time outside normal trading hours;
  - (iv) any charge for delivery in accordance with regulations made for the purposes of paragraph 87(4)(b); and
- (d) in a case where the supply is made upon a concessional benefit prescription and the Commonwealth price for the pharmaceutical benefit exceeds \$4.60—the amount received in respect of the supply is equal to the sum of the following:
  - (i) \$4.60 (less any allowable discount);
  - (ii) if an amount may be charged for the supply under subsection 87(2A)—that amount;
  - (iii) any charge for supply at a time outside normal trading hours;
  - (iv) any charge for delivery in accordance with regulations made for the purposes of paragraph 87(4)(b); and
- (e) in a case where the supply is taken, because of subsection 99(2A), (2AB) or (2B), to be a supply otherwise than under this Part, the amount charged or received in respect of the supply does not exceed the sum of the following:
  - (i) the price worked out in accordance with a determination in force under subsection (7) for the pharmaceutical benefit;
  - (ii) any amount charged or received by reason only that the supply was made at a time outside normal trading hours;
  - (iii) any amount charged or received in accordance with regulations made for the purposes of paragraph 87(4)(b).

**10 Subsection 84C(4AA)**

Omit all the words after “of this section”, substitute “if it is an early supply of a specified pharmaceutical benefit”.

**11 Subsection 84C(7)**

Omit “this section”, substitute “subparagraph (4)(e)(i)”.

**12 Section 84CA**

Repeal the section, substitute:

**84CA Transferred value**

For the purposes of subsections 84C(1C) and (1D), the transferred value for the supply of a pharmaceutical benefit, repatriation pharmaceutical benefit or out-patient medication is:

- (a) if the value for safety net purposes of the supply is less than \$4.60—that lesser amount; and
- (b) in any other case—\$4.60.

Note: The figures expressed in this section in dollars are periodically adjusted under section 99G.

**13 Subsection 87(1)**

Omit “a medical practitioner”, substitute “an approved medical practitioner”.

**14 Paragraph 87(2)(b)**

Omit “has previously been charged, for supplies of pharmaceutical benefits, an amount that is not less than the amount of the general patient safety net (within the meaning of section 99F)”, substitute “is eligible to be issued with a concession card”.

**15 Paragraph 87(2)(c)**

Repeal the paragraph.

**16 Paragraph 87(2)(e)**

Omit “or (c)”.

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**17 Subsection 87(2) (note)**

Omit “Note”, substitute “Note 1”.

**18 At the end of subsection 87(2)**

Add:

Note 2: For when a person is eligible to be issued with a concession card, see subsection 84C(1AA).

**19 Subsection 87(2AAA)**

Omit “Paragraphs (2)(b) and (c) do not apply”, substitute “Paragraph (2)(b) does not apply”.

**20 Subsections 87(2AA) and (2AB)**

Repeal the subsections.

**21 At the end of subsection 87A(3)**

Add:

Note: For when a person is eligible to be issued with a concession or entitlement card, see section 84C.

**22 Subsection 99(2AB)**

Omit “or (c)”.

**23 Section 99F (definition of *general patient reduced charge*)**

Omit “, or (c)”.

**24 Transitional provision—indexation of charges**

- (1) The repeal and substitution of paragraph 84C(4)(c) of the *National Health Act 1953* by this Schedule does not affect the indexation of general patient charge that has occurred in each year after 2005 under Division 4A of Part VII of that Act, or the continuing operation of that Division.
- (2) The repeal and substitution of paragraph 84C(4)(d) and section 84CA of that Act by this Schedule does not affect the continued indexation of concessional beneficiary charge that has occurred in each year after 2005 under Division 4A of Part VII of that Act, or the continuing operation of that Division.

## Schedule 8—Prescription and supply

### *National Health Act 1953*

#### **1 Subsection 86(1)**

Omit “furnishing”, substitute “provision”.

#### **2 Subsection 88(1)**

Repeal the subsection, substitute:

- (1) Subject to this Part, a medical practitioner is authorised to write a prescription for the supply of any pharmaceutical benefit determined from time to time by the Minister, for the purposes of this subsection, by legislative instrument.

#### **3 Subsection 88(1A)**

Omit “authorized”, substitute “authorised”.

#### **4 After subsection 88(1E)**

Insert:

- (1EA) In deciding whether a prescription for the supply of a pharmaceutical benefit should be authorised for the purposes of subsection (1), (1A), (1C), (1D) or (1E), the Minister must have regard to any advice given by the Pharmaceutical Benefits Advisory Committee.
- (1EB) The Minister is not required to determine, in relation to a pharmaceutical benefit, that at least one kind of PBS prescriber is authorised to write a prescription for the supply of the benefit.

Note: Paragraph 89(b) lists provisions that may permit supply of a pharmaceutical benefit other than on presentation of a prescription.

#### **5 Subsection 92A(3)**

Omit “or an approved medical practitioner”.

#### **6 Subsection 93A(5)**

Repeal the subsection, substitute:

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- (5) A PBS prescriber may authorise a prescribed institution to supply a pharmaceutical benefit to patients receiving treatment in the institution if:
- (a) the pharmaceutical benefit is covered by a determination made under paragraph (2)(a); and
  - (b) the PBS prescriber is authorised under section 88 to write a prescription for the supply of the pharmaceutical benefit.

### **7 After subsection 101(4AAC)**

Insert:

*Functions relating to determinations under section 88*

- (4AACAA) The Pharmaceutical Benefits Advisory Committee may give advice to the Minister as to which PBS prescribers should be authorised to write prescriptions for the supply of a pharmaceutical benefit.

### **8 Subsection 105AB(8)**

Omit “or authority of a medical practitioner or a pharmacist or the approval of a dental practitioner as a participating dental practitioner”, substitute “of a pharmacist”.

### **9 Paragraph 139A(1)(de)**

After “under section”, insert “93,”.

## Schedule 9—Data collection

### *National Health Act 1953*

#### **1 Subsection 98AC(1)**

After “subsection 99(2A),”, insert “(2AB) or (2B),”.

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*[Minister’s second reading speech made in—  
House of Representatives on 18 October 2017  
Senate on 12 February 2018]*

(227/17)

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