National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010

No. 126, 2010

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

Note: An electronic version of this Act is available in ComLaw (http://www.comlaw.gov.au/)

Contents

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No. 126, 2010

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

[*Assented to 23 November 2010*]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010*.

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
Provision(s)	**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.	23 November 2010
2. Schedule 1	1 February 2011.	1 February 2011
3. Schedules 2, 3 and 4	1 December 2010.	1 December 2010
4. Schedule 5	1 April 2012.	1 April 2012
5. Schedules 6 and 7	1 December 2010.	1 December 2010

Note: This table relates only to the provisions of this Act as originally enacted.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

Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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—Increasing the 12.5% price reduction to 16%

National Health Act 1953

1 Subsection 84(1)

Insert:

subject to a 12.5% price reduction: see subsection 99ACA(2).

2 Subsection 84(1)

Insert:

subject to a 16% price reduction: see subsection 99ACA(2A).

3 Section 99AC

Omit "12.5%" (wherever occurring), substitute "16%".

4 Paragraph 99ACA(2)(a)

After "applied", insert "before 1 February 2011".

5 After subsection 99ACA(2)

Insert:

(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.

6 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

7 Paragraphs 99ACB(2)(a) to (c)

After "12.5%", insert "or 16%".

Note 1: The heading to section 99ACB is altered by omitting "**12.5%**" and substituting "**16%**".

Note 2: The heading to subsection 99ACB(4) is altered by omitting "*12.5%*" and substituting "*16%*".

8 Subsection 99ACB(5)

Omit "12.5%", substitute "16%".

9 Paragraphs 99ACD(1A)(a) to (c)

After "12.5%", insert "or 16%".

Note 1: The heading to section 99ACD is altered by omitting "**12.5%**" and substituting "**16%**".

Note 2: The heading to subsection 99ACD(4) is altered by omitting "*12.5%*" and substituting "*16%*".

10 Subsection 99ACD(5)

After "(6)", insert ", (6A), (6B)".

11 Subsection 99ACD(5)

Omit "12.5%", substitute "16%".

12 Subsection 99ACD(6)

Repeal the subsection, substitute:

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; and

(b) because of the prior price reduction of the component, the approved price to pharmacists of the existing brand of the existing item was 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 price to pharmacists 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:

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

13 Subparagraph 99ACE(3)(a)(ii)

Repeal the subparagraph, substitute:

(ii) subject to subsections (5), (5A) and (5B), does not exceed the agreed price in force, on the day before that day, for the related brand of the related item, reduced by 16%; or

Note 1: The heading to section 99ACE is altered by omitting "**12.5%**" and substituting "**16%**".

Note 2: The heading to subsection 99ACE(2) is altered by omitting "*12.5%*" and substituting "*16%*".

14 Subparagraph 99ACE(3)(b)(ii)

Repeal the subparagraph, substitute:

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

15 Subparagraph 99ACE(4)(a)(ii)

Repeal the subparagraph, substitute:

(ii) subject to subsections (5), (5A) and (5B), do not exceed those respective prices in force on the day before that day, reduced by 16%; or

16 Subparagraph 99ACE(4)(b)(ii)

Repeal the subparagraph, substitute:

(ii) subject to subsections (5), (5A) and (5B), does not exceed the determined price in force, on the day before that day, for the related brand, reduced by 16%.

17 Subsection 99ACE(5)

Repeal the subsection, 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; and

(b) because of the prior price reduction of the component, the approved price to pharmacists of the related brand of the related item was reduced;

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

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

18 Subsection 99ACF(1) (table item 1)

Omit "12.5%", substitute "16%".

Note 1: The heading to section 99ACG is altered by inserting "**or 16%**" after "**12.5%**".

Note 2: The heading to section 99ACH is altered by omitting "**12.5%**" and substituting "**16%**".

Schedule 2—One-off 2%, 5% and 25% price reductions

National Health Act 1953

1 Subsection 84(1)

Insert:

relevant price: see subsection 99ACF(5).

2 Subsection 84(1)

Insert:

subject to an outstanding staged reduction: see subsection 99ACA(1).

3 Section 99AC

Repeal the section, substitute:

99AC What this Division is about

This Division is about price reductions for listed brands of pharmaceutical items.

Subdivision B requires there to be at least a 12.5% price reduction in the price of a new brand of a pharmaceutical item (other than a combination item) when it lists. The listing of the new brand of the pharmaceutical item also provides a trigger for price reductions to occur under Subdivision D (see section 99ACH) for:

(a) other existing brands of the pharmaceutical item; and

(b) existing brands of pharmaceutical items that have the same drug and manner of administration; and

(c) existing brands of pharmaceutical items that have a drug in the same therapeutic group and the same manner of administration.

Subdivision C sets out the circumstances in which price reductions are required for combination items.

Subdivision CA sets out the circumstances in which price reductions are required for new brands of pharmaceutical items that have the same drug as an existing brand of a pharmaceutical item that is subject to an outstanding staged reduction under section 99ACK. The listing of the new brand or brands also provides a trigger for price reductions to occur under Subdivision D (see sections 99ACM and 99ACN) for existing brands of pharmaceutical items that have that drug.

Subdivision D provides for other price reductions for pharmaceutical items (including for combination items in some cases). These price reductions:

(a) are triggered when Subdivision B applies to require a 12.5% price reduction to a new brand of a pharmaceutical item; or

(b) are triggered when Subdivision CA applies to a new brand of a pharmaceutical item that has the same drug as an existing brand of a pharmaceutical item that is subject to an outstanding staged reduction; or

(c) arise if the pharmaceutical item has a drug on F2 on a particular day.

4 Subsection 99ACA(1)

Insert:

relevant price: see subsection 99ACF(5).

5 Subsection 99ACA(1)

Insert:

subject to an outstanding staged reduction: a brand of a pharmaceutical item is ***subject to an outstanding staged reduction*** on a day if:

(a) on any day before that day, section 99ACK had applied to the brand of the pharmaceutical item; and

(b) on the day before that day, the agreed price, or the determined price and claimed price, of the brand of the pharmaceutical item had not been reduced, because of the application of section 99ACF in relation to section 99ACK or 99ACM, by 25% of the relevant price of the brand of the pharmaceutical item.

6 After Subdivision C of Division 3A of Part VII

Insert:

Subdivision CA—New brands of pharmaceutical items having drugs with outstanding staged reductions

99ACEA Price reduction for new brand of pharmaceutical item having drug with outstanding staged reductions—new brand bioequivalent or biosimilar to existing listed brand

When this section applies

(1) Subject to subsection (2), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***) on a day (the ***reduction day***) if:

(a) on the reduction day, a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item; and

(b) on the day before the reduction day:

(i) the new brand of the trigger item was not a listed brand of the trigger item; and

(ii) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and

(c) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and

(d) the trigger item and existing item have the same drug and manner of administration; and

(e) on the reduction day, either or both of the following are subject to an outstanding staged reduction:

(i) the existing brand of the existing item;

(ii) a brand (the ***related brand***) of a pharmaceutical item (the ***related item***) that has the same drug as the existing item and the trigger item.

Note 1: For the purposes of this subsection, the new brand and the existing brand may be the same brand, or the trigger item and the existing item may be the same pharmaceutical item.

Note 2: For the purposes of this subsection, the new brand and the related brand may be the same brand, or the trigger item and the related item may be the same pharmaceutical item.

Note 3: For the purposes of this subsection, the existing brand and related brand may be the same brand, or the existing item and related item may be the same pharmaceutical item.

When this section does not apply

(2) This section does not apply if, before the reduction day, this section applied to:

(a) the new brand, or another listed brand, of the trigger item; or

(b) a listed brand of another pharmaceutical item that has the same drug as the new brand of the trigger item.

Note: Subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

Price reduction

(3) The Minister:

(a) may, under section 85AD, make a price agreement for the new brand of the trigger item; and

(b) must not make a determination under section 85B in relation to the new brand of the trigger item.

(4) Subject to subsection (5), the agreed price for the new brand of the trigger item that comes into force on the reduction day must not exceed the approved price to pharmacists, on the day before the reduction day, of the existing brand of the existing item, reduced by the same amount that the agreed price or determined price of the existing brand of the existing item is reduced by on the reduction day under item 6 or 7 of the table in section 99ACF.

Apportioning if quantities are different

(5) If:

(a) the approved price to pharmacists, on the day before the reduction day, of the existing brand of the existing item is for a particular quantity or number of units of that item; and

(b) the agreed price for the new brand of the trigger item is not for the same quantity or number of units;

then, for the purposes of subsection (3), the approved price to pharmacists of the existing brand of the existing item is taken to be adjusted proportionally to what it would have been if the quantity or number of units of the existing brand of the existing item had been the same as the quantity or number of units of the new brand of the trigger item.

This section does not limit Minister's powers

(6) This section does not limit the Minister's powers, after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brand of the trigger item.

99ACEB New brands of pharmaceutical items having drug with outstanding staged reductions——new brands not bioequivalent or biosimilar to existing listed brand

When this section applies

(1) Subject to subsection (2), if:

(a) on a day (the ***reduction day***), a determination under subsection 85(6) comes into force in relation to 2 or more brands (the ***new brands***) of pharmaceutical items (the ***trigger items***); and

(b) the new brands of the trigger items:

(i) are bioequivalent or biosimilar; and

(ii) have the same drug and manner of administration; and

(c) on the day before the reduction day, the new brands of the trigger items were not listed brands of the trigger items; and

(d) on the day before the reduction day, there was not a listed brand of a pharmaceutical item that:

(i) is bioequivalent or biosimilar to the new brands of the trigger items; and

(ii) has the same drug and manner of administration as the new brands of the trigger items; and

(e) on the reduction day, a listed brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***):

(i) has the same drug as the trigger items; and

(ii) is subject to an outstanding staged reduction;

then this section applies to the new brands of the trigger items.

Note 1: For the purposes of this subsection, the new brands may be the same brand, or the trigger items may be the same pharmaceutical item.

Note 2: For the purposes of this subsection, any of the new brands and the existing brand may be the same brand, or any of the trigger items and the existing item may be the same pharmaceutical item.

When this section does not apply

(2) This section does not apply if, before the reduction day, this section applied to:

(a) the new brands, or another listed brand, of the trigger items; or

(b) a listed brand of another pharmaceutical item that has the same drug as the new brands of the trigger items.

Note: Subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

Price reduction

(3) The Minister:

(a) may, under section 85AD, make a price agreement for the new brands of the trigger items; and

(b) must not make a determination under section 85B in relation to the new brands of the trigger items.

This section does not limit Minister's powers

(4) This section does not limit the Minister's powers, after the reduction day, to make:

(a) further price agreements; or

(b) determinations under section 85B;

for the new brands of the trigger items.

7 Subsection 99ACF(1)

Omit "by the following:", substitute "by the percentage or amount specified in column 3 of the table for the section referred to in column 2.".

8 Paragraphs 99ACF(1)(d) and (e)

Repeal the paragraphs.

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

Insert:

2A	99ACIA	2%

10 Subsection 99ACF(1) (table item 4)

Repeal the item, substitute:

4	99ACK	the amount that equals the staged percentage, on the reduction day, of the relevant price for the brand of the pharmaceutical item
5	99ACL	the reduction percentage specified in subsection 99ACL(2)
6	99ACM	the amount that equals the outstanding staged percentage, on the reduction day, of the relevant price for the brand of the pharmaceutical item
7	99ACN	the reduction percentage specified in subsection 99ACN(2)
8	99ACO	5%
9	99ACP	the reduction amount specified in subsection 99ACP(2)
10	99ACQ	the reduction percentage specified in subsection 99ACQ(2)

11 Subsection 99ACF(5)

Repeal the subsection, substitute:

(5) In this section:

outstanding staged percentage for a listed brand of a pharmaceutical item on a reduction day, means 25% less each staged percentage that has applied under item 4 of the table in

subsection (1) to the brand of the pharmaceutical item on a day before the reduction day.

relevant price of a listed brand of a pharmaceutical item means:

(a) for the agreed price or determined price—the amount that was the agreed price or determined price in force in relation to the brand of the pharmaceutical item on 31 July 2008; and

(b) for the claimed price—the amount that was the claimed price in force in relation to the brand of the pharmaceutical item on the day before the reduction day.

staged percentage on a reduction day for a listed brand of a pharmaceutical item, means the percentage that is prescribed for the purposes of paragraph 99ACK(3)(b) for the reduction day.

12 After subsection 99ACG(1)

Insert:

2% reduction on 1 February 2011 does not apply if a 12.5% reduction has applied

(1A) If:

(a) on 1 December 2010, a 12.5% administrative price reduction or any of the following applies to a listed brand of a pharmaceutical item:

(i) section 99ACB;

(ii) section 99ACD or 99ACE;

(iii) subsection 99ACF(1) or (2) because of item 1 of the table in section 99ACF; and

(b) apart from this subsection, item 2A of the table would apply in relation to the brand of the pharmaceutical item, or another listed brand of the pharmaceutical item, on 1 February 2011;

then item 2A of the table does not apply on 1 February 2011 in relation to the brand of the pharmaceutical item or the other brand of the pharmaceutical item.

Note: The heading to subsection 99ACG(1) is replaced by the heading "*2% reduction on 1 August 2008, 2009 or 2010 does not apply if a 12.5% reduction has applied*".

13 Subparagraph 99ACG(2)(b)(iii)

Repeal the subparagraph, substitute:

(iii) subsection 99ACF(1) or (2) because of any item (other than item 4, 5, 6 or 7) of the table in section 99ACF;

Note 1: The heading to subsection 99ACG(2) is replaced by the heading "*Other price reductions do not apply if a price disclosure reduction has applied*".

Note 2: The heading to section 99ACI is altered by adding at the end "**on 1 August 2008, 2009 and 2010**".

14 After section 99ACI

Insert:

99ACIA 2% statutory price reduction on 1 February 2011

If:

(a) on 31 January 2011, a price agreement or a determination under section 85B is in force in relation to a listed brand of a pharmaceutical item; and

(b) on 11 October 2010, the drug in the pharmaceutical item was in Part A of F2; and

(c) on 1 February 2011, the pharmaceutical item is not an exempt item;

then this section applies to the listed brand of the pharmaceutical item on 1 February 2011.

15 Subsection 99ACK(1)

Omit "This section", substitute "Subject to subsection (1A), this section".

Note: The heading to section 99ACK is altered by omitting "**phased**" and substituting "**staged**".

16 After subsection 99ACK(1)

Insert:

(1A) This section does not apply to a brand of a pharmaceutical item on a reduction day if, on that day, section 99ACM applies or had previously applied to the brand of the pharmaceutical item.

17 At the end of Subdivision D of Division 3A of Part VII

Add:

99ACL Staged price reduction: staged reductions under section 99ACK causing statutory price reductions for other brands of pharmaceutical items having the drug

(1) This section applies to a listed brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) on a day (the ***reduction day***) if, on the reduction day:

(a) the existing brand of the existing item is not subject to an outstanding staged reduction; and

(b) a listed brand (the ***staged brand***) of a pharmaceutical item (the ***staged item***) is subject to an outstanding staged reduction; and

(c) section 99ACK applies to the staged brand of the staged item; and

(d) the existing item and the staged item have the same drug.

Note: For the purposes of paragraphs (b) and (d), the existing brand and the staged brand may be the same brand, or the existing item and the staged item may be the same pharmaceutical item.

(2) For the purposes of item 5 of the table in section 99ACF, the ***reduction percentage*** for the existing brand of the existing item is the percentage that is worked out as follows:

Method statement

Step 1. See column 3 of item 4 of the table in section 99ACF to work out the amount (the ***staged brand's reduction amount***) by which the agreed price or determined price of the staged brand of the staged item is reduced on the reduction day.

Step 2. Work out what percentage the staged brand's reduction amount represents of the agreed price or determined price of the staged brand of the staged item on the day before the reduction day.

The ***reduction percentage*** is the percentage worked out at step 2.

99ACM Staged price reduction: new brand listing bringing forward outstanding staged reductions

This section applies to a listed brand (the ***staged brand***) of a pharmaceutical item (the ***staged item***) on a day (the ***reduction day***) if, on the reduction day:

(a) the staged brand of the staged item is subject to an outstanding staged reduction; and

(b) section 99ACEA or 99ACEB applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger item***); and

(c) the staged item and the trigger item have the same drug.

Note: For the purposes of paragraphs (b) and (c), the staged brand and the new brand may be the same brand, or the staged item and the trigger item may be the same pharmaceutical item.

99ACN Staged price reduction: bringing forward outstanding staged reductions causing statutory price reduction for other brands of pharmaceutical items having the drug

(1) This section applies to a listed brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) on a day (the ***reduction day***) if, on the reduction day:

(a) the existing brand of the existing item is not subject to an outstanding staged reduction; and

(b) section 99ACM applies to a listed brand (the ***staged brand***) of a pharmaceutical item (the ***staged item***) on the reduction day; and

(c) the existing item and the staged item have the same drug.

Note: For the purposes of paragraphs (b) and (c), the existing brand and the staged brand may be the same brand, or the existing item and the staged item may be the same pharmaceutical item.

(2) For the purposes of item 7 of the table in section 99ACF, the ***reduction percentage*** for the existing brand of the existing item is the percentage that is worked out as follows:

Method statement

Step 1. See column 3 of item 6 of the table in section 99ACF to work out the amount (the ***staged brand's reduction amount***) by which the agreed price or determined price

of the staged brand of the staged item is reduced on the reduction day.

Step 2. Work out what percentage the staged brand's reduction amount represents of the agreed price or determined price of the staged brand of the staged item on the day before the reduction day.

The ***reduction percentage*** is the percentage worked out at step 2.

99ACO 5% statutory price reduction for brands of pharmaceutical items having a drug that is not subject to outstanding staged reductions

If:

(a) on 31 January 2011, a price agreement or a determination under section 85B is in force in relation to a listed brand (the ***relevant brand***) of a pharmaceutical item (the ***relevant item***); and

(b) on 11 October 2010, the drug in the relevant item was in Part T of F2; and

(c) on 1 February 2011, the relevant item is not an exempt item; and

(d) on 1 February 2011, the relevant brand of the relevant item is not subject to an outstanding staged reduction; and

(e) on 1 February 2011, there is not another listed brand of a pharmaceutical item that:

(i) is subject to an outstanding staged reduction; and

(ii) has the same drug as the relevant item;

then this section applies to the relevant brand of the relevant item on 1 February 2011.

99ACP 5% statutory price reduction for brands of pharmaceutical items subject to outstanding staged reductions

(1) If:

(a) on 31 January 2011, a price agreement or a determination under section 85B is in force in relation to a listed brand (the ***relevant brand***) of a pharmaceutical item (the ***relevant item***); and

(b) on 11 October 2010, the drug in the relevant item was in Part T of F2; and

(c) on 1 February 2011, the relevant item is not an exempt item; and

(d) on 1 February 2011, the relevant brand of the relevant item is subject to an outstanding staged reduction;

then this section applies to the relevant brand of the relevant item on 1 February 2011.

(2) For the purposes of item 9 of the table in section 99ACF, the ***reduction amount*** for the relevant brand of the relevant item is the amount that is worked out as follows:

Method statement

Step 1. Work out the relevant price of the relevant brand of the relevant item.

Step 2. Work out the amount (the ***comparison amount***) that equals 25% of the relevant price.

Step 3. Subtract the comparison amount from the relevant price.

The ***reduction amount*** is 5% of the amount worked out at step 3.

99ACQ 5% statutory price reduction for brands of pharmaceutical items having a drug that is subject to outstanding staged reductions

(1) If:

(a) on 31 January 2011, a price agreement or a determination under section 85B is in force in relation to a listed brand (the ***relevant brand***) of a pharmaceutical item (the ***relevant item***); and

(b) on 11 October 2010, the drug in the relevant item was in Part T of F2; and

(c) on 1 February 2011, the relevant item is not an exempt item; and

(d) on 1 February 2011, the relevant brand of the relevant item is not subject to an outstanding staged reduction; and

(e) on 1 February 2011:

(i) another listed brand (the ***staged brand***) of a pharmaceutical item (the ***staged item***) is subject to an outstanding staged reduction; and

(ii) the relevant item and the staged item have the same drug;

then this section applies to the relevant brand of the relevant item on 1 February 2011.

(2) For the purposes of item 10 of the table in section 99ACF, the ***reduction percentage*** for the relevant brand of the relevant item is the percentage that is worked out as follows:

Method statement

Step 1. See column 3 of item 9 of the table in section 99ACF to work out the amount (the ***staged brand's reduction amount***) by which the agreed price or determined price of the staged brand of the staged item is reduced on the reduction day.

Step 2. Work out what percentage the staged brand's reduction amount represents of the agreed price or determined price of the staged brand of the staged item on the day before the reduction day.

The ***reduction percentage*** is the percentage worked out at step 2.

18 After paragraph 99AEI(2)(d)

Insert:

(da) the new brand of the trigger item referred to in section 99ACEA; or

(db) one of the new brands of the triggers items referred to in section 99ACEB; or

19 At the end of subsection 99AEI(3)

Add:

; or (c) if subsection 99ACEA(1) applied to the delisted brand of the existing item—for the purposes of subsection 99ACEA(2),

subsection 99ACEA(1) is taken not to have applied to the delisted brand of the existing item; or

(d) if subsection 99ACEB(1) applied to the delisted brand of the existing item—for the purposes of subsection 99ACEB(2), subsection 99ACEB(1) is taken not to have applied to the delisted brand of the existing item.

Schedule 3—Merging of Part A and Part T of F2

National Health Act 1953

1 At the end of section 84AD

Add:

(6) Regulations made for subsection (2) or (4) cease to be in force on 1 December 2010.

(7) Regulations made for subsection (5), to the extent that they prescribe that a drug is in Part A or Part T of F2, cease to be in force on 1 December 2010.

Note: Subsection (7) does not affect the regulations to the extent that they prescribe that a drug is on F1 or F2.

2 Subsection 85AC(5)

Omit "1 January 2011", substitute "1 December 2010".

Schedule 4—Price disclosure

National Health Act 1953

1 Section 99AD

Omit:

> • Subdivision C sets out the situations when the responsible person for the brand of the pharmaceutical item is required to comply with the price disclosure requirements. This could be because compliance with the price disclosure requirements is mandatory, or because the responsible person volunteers to comply with them.

Substitute:

> • The price disclosure requirements generally apply in relation to brands of pharmaceutical items that have a drug on F2.

2 Section 99ADA

Repeal the section, substitute:

99ADA Division does not apply to exempt items

This Division does not apply to brands of exempt items.

3 Subsection 99ADB(1) (definition of *adjusted approved ex-manufacturer price*)

Repeal the definition, substitute:

adjusted approved ex-manufacturer price of a brand of a pharmaceutical item is:

(a) on 1 April 2012—the amount worked out in accordance with section 99ADJ, if that section so provides; or

(b) otherwise—the amount equal to the amount of the weighted average disclosed price of the brand of the pharmaceutical item.

4 Subsection 99ADB(1)

Insert:

agreed quantity, for a brand of a pharmaceutical item, is the quantity or number of units of the pharmaceutical item by reference to which the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists has been:

(a) agreed under section 85AD; or

(b) determined under subsection 85B(2).

5 Subsection 99ADB(1)

Insert:

applicable approved ex-manufacturer price of a brand of a pharmaceutical item is the approved ex-manufacturer price of the brand on the last day of the period in respect of which the weighted average disclosed price of the brand of the pharmaceutical item is determined.

6 Subsection 99ADB(1)

Insert:

unadjusted price reduction for a brand of a pharmaceutical item is the difference between:

(a) the applicable approved ex-manufacturer price of the brand of the pharmaceutical item; and

(b) the weighted average disclosed price of the brand of the pharmaceutical item;

expressed as a percentage of that applicable approved ex-manufacturer price.

7 Subsection 99ADB(1) (definition of *weighted average disclosed price*)

Omit "or (5)".

8 Subsection 99ADB(5)

Repeal the subsection.

9 Subsection 99ADB(6)

Omit "or (5)".

10 At the end of section 99ADB

Add:

(7) A determination made under subsection (4) in relation to a brand of a pharmaceutical item may include:

(a) the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item; and

(b) the adjusted approved price to pharmacists of the brand of the pharmaceutical item.

11 Subdivision C of Division 3B of Part VII (heading)

Repeal the heading.

12 Sections 99ADD and 99ADE

Repeal the sections, substitute:

99ADD When the price disclosure requirements apply

The responsible person for a listed brand of a pharmaceutical item that has a drug on F2 is required to comply with the price disclosure requirements for each supply of the brand of the pharmaceutical item.

13 After paragraph 99ADH(1)(a)

Insert:

(aa) the Minister, by legislative instrument, determines a day (the ***reduction day***) for the purposes of this section in relation to the brand of the pharmaceutical item; and

14 Paragraph 99ADH(1)(b)

After "pharmaceutical item", insert "on the reduction day".

15 Paragraphs 99ADH(1)(c) and (d)

Repeal the paragraphs, substitute:

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

16 Subsection 99ADH(2)

Repeal the subsection, substitute:

(2) For the purposes of paragraph 99ADH(1)(aa), the reduction day must be a prescribed day.

17 Subsection 99ADH (6)

Repeal the subsection.

18 At the end of Subdivision E of Division 3B of Part VII

Add:

99ADJ Minimum average 23% price reduction for some brands of pharmaceutical items

(1) If:

(a) this section applies to a brand of a pharmaceutical item; and

(b) the average unadjusted price reduction, worked out under subsection (3), for all the brands of pharmaceutical items to which this section applies is less than 23%;

the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item, on 1 April 2012, is the amount worked out under subsection (6).

Brands of pharmaceutical items to which this section applies

(2) This section applies to a brand of a pharmaceutical item (the ***relevant brand***) if:

(a) the drug in the pharmaceutical item is on F2 on 1 December 2010; and

(b) no requirement to comply with price disclosure requirements has arisen under former subsection 99ADD(1) before 1 December 2010 in relation to:

(i) the relevant brand; or

(ii) any other brand of any pharmaceutical item having that drug and having the same manner of administration as the relevant brand.

The average unadjusted price reduction

(3) The ***average unadjusted price reduction*** for all the brands of pharmaceutical items to which this section applies is the percentage worked out as follows:

Method statement

Step 1. For each brand of a pharmaceutical item to which this section applies, multiply:

(a) the applicable approved ex-manufacturer price of the brand; by

(b) the total number of the supplies of the agreed quantity for the brand that were supplies in respect of which the Commonwealth provided benefits under section 85, during the period of 10 months starting on 1 December 2010.

Step 2. For each amount worked out under step 1, work out the amount of that step 1 amount that represents a percentage equal to the unadjusted price reduction for the brand.

Step 3. Divide:

(a) the sum of all the amounts worked out under step 2 for all of the brands of pharmaceutical items to which this section applies; by

(b) the sum of all the amounts worked out under step 1 for all of those brands.

Step 4. The amount worked out under step 3, multiplied by 100 and expressed as a percentage, is the ***average unadjusted price reduction*** for all the brands of pharmaceutical items to which this section applies.

(4) For the purposes only of subsection (3), if:

(a) a combination item has a drug to which subsection 85AB(5) applies; and

(b) there is only one listed brand (the ***single brand***) of the combination item; and

(c) a pharmaceutical item has a drug that is a listed drug (the ***component drug***) that the drug referred to in paragraph (a) contains; and

(d) a brand of the pharmaceutical item (a ***related brand***):

(i) is a brand to which this section applies; and

(ii) has the same manner of administration as the single brand;

then:

(e) the single brand is taken to be a brand of a pharmaceutical item to which this section applies; and

(f) subject to subsection (5), the unadjusted price reduction for the single brand is taken to be the percentage by which the approved ex-manufacturer price of the single brand would be reduced if the approved price to pharmacists of the brand were to be reduced under section 99ACC to take account of:

(i) the unadjusted price reduction for the related brand being applied to the component drug; and

(ii) in a case where the single brand contains one or more other component drugs in relation to which there are one or more other related brands of pharmaceutical items—the unadjusted price reductions for the other related brands being applied to the other component drugs.

(5) The unadjusted price reduction for the single brand is taken to be 0% if the single brand is a brand of a combination item in relation to which the Pharmaceutical Benefits Advisory Committee has advised the Minister under subsection 101(4AC).

Working out the adjusted approved ex-manufacturer price

(6) If subsection (1) applies in relation to a brand of a pharmaceutical item, the adjusted approved ex-manufacturer price of the brand is worked out as follows:

Method statement

Step 1.	Divide 23% by the average unadjusted price reduction, worked out under subsection (3), for all the brands of pharmaceutical items to which this section applies. The result is the ***guaranteed adjustment proportion***.
Step 2.	For each of those brands of pharmaceutical items, multiply the guaranteed adjustment proportion by the unadjusted price reduction for the brand of the pharmaceutical item.
Step 3.	For each of those brands, reduce the applicable approved ex-manufacturer price of the brand by the percentage worked out under step 2.
Step 4.	If the lowest price disclosed, in compliance with price disclosure requirements under section 99ADD, for the pharmaceutical item during the period of 10 months starting on 1 December 2010, is higher than the amount worked out under step 3, work out the difference between: (a) the applicable approved ex-manufacturer price of the brand; and (b) that lowest price; expressed as a percentage of that applicable approved ex-manufacturer price.
Step 5.	The ***GAP-adjusted reduction*** for the brand is: (a) unless step 4 applies—the percentage worked out under step 2; or (b) if step 4 applies—the percentage worked out under step 4.
Step 6.	Work out, under subsection (3), the average unadjusted price reduction for all the brands of pharmaceutical items to which this section applies, as if the unadjusted price reduction for each brand were the GAP-adjusted reduction for the brand.

Step 7. If the average unadjusted price reduction worked out under step 6 is at least 23%, reduce the applicable approved ex-manufacturer price of the brand by a percentage of that price equal to the GAP-adjusted reduction for the brand. The result is the ***GAP-adjusted approved ex-manufacturer price*** of the brand.

Step 8. If step 7 applies, the ***adjusted approved ex-manufacturer price*** of a brand to which this section applies is the GAP-adjusted approved ex-manufacturer price of the brand.

Step 9. If the average unadjusted price reduction worked out under step 6 is less than 23%, repeat steps 1 to 6, as many times as necessary until step 7 is satisfied, as if:

(a) the reference in step 1 to the average unadjusted price reduction were a reference to the average unadjusted price reduction last worked out under step 6; and

(b) the reference in step 2 to the unadjusted price reduction for a brand of a pharmaceutical item were a reference to the GAP-adjusted reduction for the brand last worked out under step 5.

(7) However, if, in applying or repeating steps 1 to 6 of the method statement in subsection (6), step 4 of the method statement applies in relation to all the brands of pharmaceutical items to which this section applies:

(a) steps 6 to 9 of the method statement cease to apply; and

(b) the ***adjusted approved ex-manufacturer price*** of a brand to which this section applies is worked out by reducing the applicable approved ex-manufacturer price of the brand by a percentage of that price equal to the GAP-adjusted reduction for the brand last worked out under step 5 of the method statement.

Effect of the unadjusted price reduction for a brand being less than 10%

(8) If, but for this subsection, the unadjusted price reduction for a brand of a pharmaceutical item would be less than 10%, the unadjusted price reduction for the brand is taken to be 0% for the purposes of:

(a) working out under subsection (3) the average unadjusted price reduction for all the brands of pharmaceutical items to which this section applies; and

(b) working out under subsection (6) the adjusted approved ex-manufacturer price of the brand.

The weighted average disclosed price of a brand

(9) Until the Minister determines the weighted average disclosed price of a brand of a pharmaceutical item in respect of the period of 10 months ending on 30 September 2011, that weighted average disclosed price is taken, for the purposes of any reference in this section to:

(a) the applicable approved ex-manufacturer price of the brand; or

(b) the unadjusted price reduction for the brand;

to be the price worked out in accordance with the regulations made for the purposes of subsection 99ADB(6).

19 Section 99AEL

Repeal the section.

20 Application provision

(1) The amendments made by items 2, 12 and 19 of this Schedule apply in relation to supplies of brands of pharmaceutical items occurring on or after the commencement of this item.

(2) The amendments made by items 7 to 9 and 13 to 17 of this Schedule apply if the period in respect of which the weighted average disclosed price of the relevant brand of the relevant pharmaceutical item is determined ends on or after the commencement of this item.

Schedule 5—Under co-payment data

National Health Act 1953

1 At the end of Division 2 of Part VII

Add:

98AC Information about supplies

(1) An approved supplier that supplies a pharmaceutical benefit (including a supply taken, because of subsection 99(2A), to be a supply otherwise than under this Part):

(a) must give to the Secretary, in relation to the supply of that benefit, the information specified in rules made by the Minister under paragraph (4)(a); and

(b) must give the information in accordance with the rules made by the Minister under paragraph (4)(b).

(2) Subsection (1) does not apply if the approved supplier makes, or proposes to make, a claim for payment in relation to the supply of the pharmaceutical benefit under section 99AAA.

(3) Subject to the rules made by the Minister under paragraph (4)(b), subsections 99AAA(4) and (5) and section 99AAB (about the procedures for giving information) apply in relation to the giving of information under this section in the same way as they apply in relation to the giving of information under section 99AAA.

(4) The Minister must, by legislative instrument, make:

(a) rules specifying the information to be given to the Secretary by approved suppliers in relation to the supply by them of pharmaceutical benefits; and

(b) rules defining the procedures to be followed by approved suppliers in giving information to the Secretary in relation to the supply by them of pharmaceutical benefits.

(5) In making rules for the purposes of paragraph (4)(b), the Minister may define different procedures:

(a) for the giving of information by electronic means; and

(b) for the giving of information otherwise than by electronic means.

(6) Rules made under this section may be set out in the same document as rules made under subsection 99AAA(8).

2 Subsection 99AAA(8)

Omit "instrument in writing", substitute "legislative instrument".

3 Subsection 99AAA(9)

Repeal the subsection.

4 Paragraph 135AA(1)(c)

Repeal the paragraph, substitute:

(c) was obtained by the agency or any other agency in connection with:

(i) a claim for payment of a benefit under the Medicare Benefits Program or the Pharmaceutical Benefits Program; or

(ii) a supply of a pharmaceutical benefit to which subsection 98AC(1) applies.

5 Subparagraph 135AA(2)(a)(i)

After "made", insert ", or who provided the pharmaceutical benefit".

6 Subparagraph 135AA(2)(a)(ii)

After "goods", insert "or the pharmaceutical benefit".

7 After subsection 135AA(5A)

Insert:

(5B) Nothing in this section, or in the guidelines issued by the Information Commissioner, precludes the inclusion, in a database of information:

(a) held by the Medicare Australia CEO; and

(b) relating to supplies of pharmaceutical benefits to which subsection 98AC(1) applies;

of the pharmaceutical entitlements number applicable to the person to whom each such supply relates:

(c) as a person covered by a benefit entitlement card; or

(d) as a person included within a class identified by the Minister in a determination under subsection 86E(1).

Schedule 6—Special arrangements

Part 1—Main amendments

National Health Act 1953

1 Subsection 84(1)

Insert:

pharmaceutical benefit has a drug: see subsection 84ABA(3).

2 Subsection 84(1) (definition of *special pharmaceutical product*)

Repeal the definition.

3 At the end of section 84ABA

Add:

(3) A reference in this Part to a pharmaceutical benefit having a drug is a reference to the pharmaceutical benefit having the drug or medicinal preparation referred to in paragraph (a) of the definition of ***pharmaceutical benefit*** in subsection 84(1) in relation to the pharmaceutical benefit.

Note: The heading to section 84ABA is altered by omitting "**or combination items**" and substituting "**, combination items or pharmaceutical benefits**".

4 Subsection 85(1) (note)

Repeal the note, substitute:

Note 1: While most pharmaceutical benefits are generally available for supply under this Part, some pharmaceutical benefits (see section 85AA) can only be supplied under this Part in accordance with special arrangements under section 100.

Note 2: Special arrangements under section 100 can modify the effect of this Part in relation to the supply of pharmaceutical benefits that are covered by the arrangements (see subsection 100(3)).

Note: The following heading to subsection 85(1) is inserted "*Pharmaceutical benefits*".

5 At the end of subsection 85(2)

Add:

Note 1: The Minister cannot make a declaration under this subsection in relation to a drug or medicinal preparation unless the Pharmaceutical Benefits Advisory Committee has recommended that the drug or medicinal preparation be declared (see subsections 101(4) and (4A)).

Note 2: If the Minister makes a declaration in relation to a drug or medicinal preparation under this subsection, the Minister cannot vary or revoke that declaration so as to delist the drug or medicinal preparation without first obtaining the Pharmaceutical Benefits Advisory Committee's advice (see subsection 101(4AAB)).

Note: The following heading to subsection 85(2) is inserted "*Drugs etc.*".

6 Subsection 85(2A)

Repeal the subsection, substitute:

Drugs etc. that can only be supplied under special arrangements

(2A) If:

(a) the Minister makes a declaration under subsection (2) in relation to a drug or medicinal preparation (the ***drug***); and

(b) the Pharmaceutical Benefits Advisory Committee has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100;

then the Minister must, by legislative instrument, declare that the drug can only be supplied under such special arrangements.

Note: If the Minister makes a declaration in relation to a drug or medicinal preparation under this subsection, the Minister cannot vary or revoke that declaration without first satisfying the conditions set out in subsection 101(4AAF).

7 Subsections 85(2AA), (2AB) and (2AC)

Repeal the subsections.

Note 1: The following heading to subsection 85(3) is inserted "*Forms*".

Note 2: The following heading to subsection 85(5) is inserted "*Manners of administration*".

Note 3: The following heading to subsection 85(6) is inserted "*Brands*".

8 At the end of section 85

Add:

Prescriptions of pharmaceutical benefits in certain circumstances

(7) The Minister may, by legislative instrument, determine:

(a) that a particular pharmaceutical benefit is to be a relevant pharmaceutical benefit for the purposes of section 88A; and

(b) the circumstances in which a prescription for the supply of the pharmaceutical benefit may be written.

Pharmaceutical benefits that can only be supplied under special arrangements

(8) The Minister may, by legislative instrument, determine that:

(a) a particular pharmaceutical benefit (other than a pharmaceutical benefit that has a drug covered by subsection (2A)) can only be supplied under special arrangements under section 100; or

(b) one or more of the circumstances in which a prescription for the supply of a pharmaceutical benefit may be written under paragraph (7)(b) are circumstances in which the benefit can only be supplied under special arrangements under section 100.

9 After section 85

Insert:

85AA Pharmaceutical benefits that can only be supplied under special arrangements

(1) If the Minister makes a declaration under subsection 85(2A) in relation to a drug or medicinal preparation (the ***drug***), then every pharmaceutical benefit that has that drug can only be supplied under this Part in accordance with special arrangements under section 100.

(2) If the Minister makes a determination under paragraph 85(8)(a) in relation to a pharmaceutical benefit, then that pharmaceutical benefit can only be supplied under this Part in accordance with special arrangements under section 100.

(3) If the Minister makes a determination under paragraph 85(8)(b) about the circumstances in which a pharmaceutical benefit can only be supplied under special arrangements under section 100, then, in those circumstances, the pharmaceutical benefit can only be supplied under this Part in accordance with those arrangements.

10 Section 88A

Omit "85(2A)" (wherever occurring), substitute "85(7)".

11 Subsection 100(1)

Omit "providing that an adequate supply of special pharmaceutical products", substitute ", or in relation to, providing that an adequate supply of pharmaceutical benefits".

12 Paragraph 100(1)(b)

Repeal the paragraph, substitute:

(b) who are receiving treatment in circumstances in which pharmaceutical benefits (other than those to which subsection (1A) applies) are inadequate for that treatment; or

(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

13 After subsection 100(1)

Insert:

(1A) This subsection applies to:

(a) pharmaceutical benefits to which subsection 85AA(1) or (2) applies; and

(b) pharmaceutical benefits supplied in the circumstances referred to in subsection 85AA(3).

14 Subsection 100(3)

Omit "This Part has", substitute "This Part, and regulations or other instruments made for the purposes of this Part, have".

15 Section 100AA

Repeal the section.

16 Subsections 101(3) and (3A)

Omit "or special pharmaceutical products".

17 Paragraphs 101(3B)(a) and (b)

Omit "or special pharmaceutical products".

18 Subsection 101(3C)

Omit "or special pharmaceutical products".

Note: The following heading to subsection 101(4) is inserted "*Functions relating to declarations under subsection 85(2)*".

19 After subsection 101(4A)

Insert:

(4AAA) The Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation.

(4AAB) If:

(a) under subsection (4AAA), the Minister proposes to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation; and

(b) on and after the day the revocation or variation comes into force, the drug or medicinal preparation would cease to be a listed drug;

then, before making the revocation or variation, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation.

(4AAC) An advice under subsection (4AAB) must be laid before each House of the Parliament with the declaration under subsection (4AAA) to which the advice relates.

Functions relating to declarations under subsection 85(2A)

(4AAD) The Pharmaceutical Benefits Advisory Committee must make recommendations to the Minister from time to time as to the drugs and medicinal preparations which it considers should be made available only under special arrangements under section 100.

(4AAE) The Minister may, by legislative instrument, revoke or vary a declaration under subsection 85(2A) in relation to a drug or medicinal preparation.

(4AAF) If:

(a) under subsection (4AAE), the Minister proposes to revoke or vary a declaration under subsection 85(2A) in relation to a drug or medicinal preparation (the ***drug***); and

(b) on and after the day the revocation or variation comes into force, the drug could be supplied under this Part otherwise than under special arrangements under section 100;

then the Minister can only make the revocation or variation if:

(c) the Minister also revokes or varies the declaration under subsection 85(2), in accordance with subsections (4AAA), (4AAB) and (4AAC) of this section, so that the drug ceases to be a listed drug on and after the day the revocation or variation of the subsection 85(2) declaration comes into force; or

(d) the Pharmaceutical Benefits Advisory Committee recommends against the Minister taking the action in paragraph (c).

20 Sections 114 and 116

Omit "or special pharmaceutical products".

21 Subsection 133(1)

Omit "or special pharmaceutical products".

22 Subsections 134(1) and (2)

Omit "or special pharmaceutical product".

23 Subsection 135A(5A)

Omit "or special pharmaceutical products may be published in spite of the fact that the manufacturer of any of those benefits or products", substitute "may be published in spite of the fact that the manufacturer of any of those benefits".

24 Subsection 135A(5C)

Omit "or special pharmaceutical product" (wherever occurring).

25 Subsection 135A(8)

Omit "or special pharmaceutical product shall not be divulged in pursuance of subsection (6) or (7) in a manner that is likely to enable the identification of the person to whom that service was rendered, that treatment or care was provided or that benefit or product", substitute "must not be divulged in pursuance of subsection (6) or (7) in a manner that is likely to enable the identification of the person to whom that service was rendered, that treatment or care was provided or that benefit".

26 Subsection 135A(24) (definition of *special pharmaceutical product*)

Repeal the definition.

27 Subsection 135AA(11) (definition of *Pharmaceutical Benefits Program*)

Omit "and special pharmaceutical products".

Part 2—Consequential amendments

Health Insurance Act 1973

28 Subsection 81(1) (definition of *pharmaceutical benefit*)

Repeal the definition, substitute:

> ***pharmaceutical benefit*** means a pharmaceutical benefit as defined in Part VII of the *National Health Act 1953*.

Medicare Australia Act 1973

29 Section 3 (definition of *pharmaceutical benefit*)

Repeal the definition, substitute:

> ***pharmaceutical benefit*** means a pharmaceutical benefit as defined in Part VII of the *National Health Act 1953*.

Part 3—Application and transitional provisions

30 Definitions

In this Part:

commencement means the commencement of this Schedule.

main Act means the *National Health Act 1953*.

31 Application of amendments

The amendments made by this Schedule apply on and after commencement in relation to:

(a) declarations or determinations that are made on or after commencement under section 85 of the main Act (including declarations or determinations that are made in relation to a drug or medicinal preparation that is covered by special arrangements that were made before commencement under section 100 of the main Act); and

(b) special arrangements that are made on or after commencement under section 100 of the main Act.

32 Transitional provisions relating to legislative instruments made before commencement

(1) If the legislative instrument that:

(a) is known as "Instrument Number PB 14 of 2010"; and

(b) was registered on 17 March 2010 under the Federal Register of Legislative Instruments established under the *Legislative Instruments Act 2003* (registration number F2010L00659);

is in force immediately before commencement, then, on and after commencement, the drugs and medicinal preparations (the ***drugs***) that are specified in Schedule 6 to that instrument are to be treated (and may be dealt with) as if a declaration had been made in relation to the drugs under subsections 85(2) and (2A) of the main Act.

(2) If the legislative instrument that:

(a) is known as "Instrument Number PB 41 of 2010"; and

(b) was registered on 30 April 2010 under the Federal Register of Legislative Instruments established under the *Legislative Instruments Act 2003* (registration number F2010L01083);

is in force immediately before commencement, then, on and after commencement, the drug or medicinal preparation (the ***drug***) specified in Schedule 1 to that instrument is to be treated (and may be dealt with) as if a declaration had been made in relation to the drug under subsections 85(2) and (2A) of the main Act.

(3) If a legislative instrument that was made under subsection 85(2A) of the main Act is in force immediately before commencement, then, on and after commencement, that legislative instrument is to be treated (and may be dealt with) as if it had been made under subsection 85(7) of the main Act.

33 Transitional provisions relating to PBAC advice or recommendations given before commencement

(1) If, before commencement, the Minister had obtained the advice of the Pharmaceutical Benefits Advisory Committee under subsection 85(2AB) of the main Act in relation to a proposed revocation or variation under subsection 85(2AA) of that Act, then, on and after commencement, that advice is to be treated (and may be dealt with) as if:

(a) it had been obtained under subsection 101(4AAB) of that Act; and

(b) it related to a proposed revocation or variation under subsection 101(4AAA) of that Act.

(2) If, before commencement, the Pharmaceutical Benefits Advisory Committee had recommended under paragraph 100AA(4)(a) of the main Act that the Minister make a declaration in relation to a drug or medicinal preparation under subsection 100AA(2) of that Act, then, on and after commencement, that recommendation is to be treated (and may be dealt with) as if:

(a) it had been obtained under subsections 101(4) and (4AAD) of that Act; and

(b) it related to declarations under subsections 85(2) and (2A) of that Act.

(3) If, before commencement, the Minister had obtained the advice of the Pharmaceutical Benefits Advisory Committee under subsection

100AA(5) of the main Act in relation to the revocation or variation of a declaration under subsection 100AA(2) of that Act, then, on and after commencement, that advice is to be treated (and may be dealt with) as if:

(a) it had been obtained under subsection 101(4AAB) of that Act; and

(b) it related to a revocation or variation of a declaration under subsection 85(2) of that Act.

Schedule 7—Miscellaneous

National Health Act 1953

1 Subsection 85(2)

Omit "Subject to subsection (3), the", substitute "The".

2 Subparagraph 99ACA(2)(a)(ii)

Omit "that section", substitute "section 99ACF".

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

Omit "that section", substitute "section 99ACF".

4 Subsection 99ACC(6)

Repeal the subsection, substitute:

Subject to statutory price reduction

(6) A listed component drug contained in a drug in a combination item becomes ***subject to statutory price reduction*** if:

(a) section 99ACB, subsection 99ACF(1) or (2) (because of item 1 in the table in section 99ACF) or section 99ADH 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; or

(b) subsection 99ACF(1) or (2) (because of any of the items (other than item 1) in the table in section 99ACF) has applied to a listed brand of a pharmaceutical item that has the listed component drug.

5 Subsection 99ACD(1)

Omit "subsections (2) and (3)", substitute "subsections (1A) and (2)".

6 Subparagraph 99ACG(1)(a)(iii)

Omit "that section", substitute "section 99ACF".

[*Minister's second reading speech made in—*
House of Representatives on 29 September 2010
Senate on 25 October 2010]

(186/10)