



National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007

No. 111, 2007

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

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No. 111, 2007

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

[Assented to 28 June 2007]

The Parliament of Australia enacts:

1 Short title

This Act may be cited as the *National Health Amendment
(Pharmaceutical Benefits Scheme) Act 2007*.

2 Commencement

This Act commences on 1 August 2007.

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Each Act that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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

Part 1—Amendments

National Health Act 1953

1 After subsection 4(1C)

Insert:

- (2) A reference in this Act to a prescription for the supply of a pharmaceutical benefit is a reference to a prescription written in accordance with subsection 88(1) or (1A).

2 Subsection 84(1)

Insert:

agreed price means the amount in force under a price agreement.

3 Subsection 84(1)

Insert:

approved price to pharmacists has the meaning given by subsection 98B(3).

5 Subsection 84(1) (definition of *brand*)

Repeal the definition, substitute:

brand of a pharmaceutical item means:

- (a) the trade name under which the person who is or will be the responsible person supplies the pharmaceutical item; or
(b) if there is no trade name—the name of the person who is or will be the responsible person.

6 Subsection 84(1)

Insert:

claimed price means the amount specified in a determination in force under subsection 85B(3).

7 Subsection 84(1)

Insert:

co-marketed brands has the meaning given by section 84AE.

8 Subsection 84(1)

Insert:

combination item means a pharmaceutical item that has a drug that contains at least 2 other drugs or medicinal preparations, at least one of which is a listed drug.

9 Subsection 84(1)

Insert:

combination item has a drug means the combination item has the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item that is the combination item.

10 Subsection 84(1)

Insert:

determined price means the amount specified in a determination in force under subsection 85B(2).

11 Subsection 84(1)

Insert:

drug in a combination item means the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item that is the combination item.

12 Subsection 84(1)

Insert:

drug in a pharmaceutical item means the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item.

13 Subsection 84(1)

Insert:

drug is in Part A of F2 has the meaning given by section 84AD.

14 Subsection 84(1)

Insert:

drug is in Part T of F2 has the meaning given by section 84AD.

15 Subsection 84(1)

Insert:

drug is on F1 has the meaning given by section 84AC.

16 Subsection 84(1)

Insert:

drug is on F2 has the meaning given by section 84AC.

17 Subsection 84(1)

Insert:

exempt item means a pharmaceutical item determined by the Minister under section 84AH to be an exempt item.

18 Subsection 84(1)

Insert:

listed brand of a pharmaceutical item means a brand of the pharmaceutical item in relation to which a determination under subsection 85(6) is in force.

19 Subsection 84(1)

Insert:

listed drug means a drug or medicinal preparation in relation to which a declaration under subsection 85(2) is in force.

20 Subsection 84(1) (definition of *pharmaceutical benefit*)

Repeal the definition, substitute:

pharmaceutical benefit means the following:

- (a) if a declaration under subsection 85(2) is in force in relation to a drug or medicinal preparation (the *drug*) and paragraph (b), (c) and (d) do not apply—the drug;
- (b) if a determination under subsection 85(3) is in force in relation to a form of the drug and paragraph (c) and (d) do not apply—the drug in that form;
- (c) if a determination under subsection 85(5) is in force in relation to a manner of administration of that form of the drug and paragraph (d) does not apply—the drug in that form with that manner of administration;
- (d) if a determination under subsection 85(6) is in force in relation to a brand of a pharmaceutical item that is the drug in that form with that manner of administration—that brand of the drug in that form with that manner of administration.

21 Subsection 84(1)

Insert:

pharmaceutical item has the meaning given by section 84AB.

22 Subsection 84(1)

Insert:

pharmaceutical item has a drug means the pharmaceutical item has the drug referred to in paragraph 84AB(a) in the application of that paragraph to the pharmaceutical item.

23 Subsection 84(1)

Insert:

price agreement means an agreement under section 85AD.

24 Subsection 84(1)

Insert:

price determination means a determination under subsection 85B(2).

25 Subsection 84(1)

Insert:

responsible person for a brand of a pharmaceutical item means the person determined by the Minister under section 84AF to be the responsible person for the brand of the pharmaceutical item.

26 Subsection 84(1)

Insert:

special patient contribution has the meaning given by subsection 85B(4).

27 Subsection 84(1)

Insert:

therapeutic group means a therapeutic group determined by the Minister under section 84AG.

28 After subsection 84(1A)

Insert:

(1B) If:

- (a) a prescription for the repeated supply of a pharmaceutical benefit (the *prescribed benefit*) identifies the pharmaceutical benefit to be supplied by specifying a listed brand of a pharmaceutical item; and
- (b) the pharmaceutical benefit supplied (the *supplied benefit*) on the repeated supply is another listed brand of the pharmaceutical item;

then the supplied benefit is taken to be the repeated supply, upon the prescription, of the prescribed benefit.

29 Paragraph 84AAA(1)(a)

Omit “of the same pharmaceutical benefit to the person”, substitute “to the person of a pharmaceutical benefit that has the same pharmaceutical item”.

30 Paragraph 84AAA(1)(b)

Before “the pharmaceutical benefit”, insert “the pharmaceutical item in”.

31 Subsection 84AAA(2)

Omit “benefits”, substitute “items”.

32 Subsection 84AAA(3)

Omit “Pharmaceutical benefits”, substitute “A pharmaceutical item”.

33 Paragraphs 84AAA(3)(a) and (b)

Omit “the pharmaceutical benefit”, substitute “a pharmaceutical benefit that has the pharmaceutical item”.

34 At the end of Division 1 of Part VII

Add:

84AB Pharmaceutical items

If:

- (a) a declaration under subsection 85(2) is in force in relation to a drug or medicinal preparation (the *drug*); and
- (b) a determination under subsection 85(3) is in force in relation to a form of the drug; and
- (c) a determination under subsection 85(5) is in force in relation to a manner of administration of that form of the drug;

then the drug in that form with that manner of administration is a *pharmaceutical item*.

84AC When listed drug is on F1 or F2

F1

- (1) A *drug is on F1* if there is a determination in force under section 85AB or 99AEJ that the drug is on F1.
- (2) A *drug is on F1* if:
 - (a) the regulations prescribe that the drug is on F1; and
 - (b) there is not a determination under section 85AB in force that the drug is on F2.

F2

- (3) A *drug is on F2* if there is a determination in force under section 85AB that the drug is on F2.
- (4) A *drug is on F2* if the regulations prescribe that the drug is on F2.

Regulations

- (5) On the day on which this section commences, the regulations may prescribe that a drug or medicinal preparation that is a listed drug on that day is on F1 or F2.

84AD When listed drug is in Part A or Part T of F2

Part A

- (1) A **drug is in Part A of F2** if there is a determination in force under section 85AC that the drug is in Part A of F2.
- (2) A **drug is in Part A of F2** if the regulations prescribe that the drug is in Part A of F2.

Part T

- (3) A **drug is in Part T of F2** if there is a determination in force under section 85AC that the drug is in Part T of F2.
- (4) A **drug is in Part T of F2** if the regulations prescribe that the drug is in Part T of F2.

Regulations

- (5) Regulations made under subsection 84AC(5) that prescribe that a drug is on F2 may also prescribe that the drug is in Part A or Part T of F2.

84AE Co-marketed brands

When co-marketed brands are to be treated as one brand

- (1) For the purposes of section 85AB, 2 or more brands of a pharmaceutical item that are co-marketed brands of the pharmaceutical item are to be treated as if they were only one brand of the pharmaceutical item.

Meaning of co-marketed brands

- (2) 2 or more brands of a pharmaceutical item are **co-marketed brands** of the pharmaceutical item if:

- (a) the Minister determines under subsection (3) that the brands are co-marketed brands of the pharmaceutical item; or
- (b) the regulations prescribe that the brands are co-marketed brands of the pharmaceutical item.

Ministerial determination

- (3) The Minister may, by legislative instrument, determine that 2 or more brands (the *co-marketed brands*) of a pharmaceutical item (the *co-marketed item*) are co-marketed brands of the co-marketed item if the co-marketed brands satisfy the following:
 - (a) within 4 months of the first of the co-marketed brands of the co-marketed item being included on the Australian Register of Therapeutic Goods, applications are made to include the other co-marketed brands of the co-marketed item on the Register;
 - (b) the first determination that is made under subsection 85(6) in relation to a brand of the co-marketed item is made only in relation to the co-marketed brands of the co-marketed item;
 - (c) no determination is in force under subsection 85(6) in relation to a brand of a pharmaceutical item that has the same drug as the co-marketed item (other than the co-marketed brands of the co-marketed item).

Note: For the purposes of paragraph (c), the brand mentioned in that paragraph may be same as one of the co-marketed brands, or the pharmaceutical item mentioned in that paragraph may be the same as the co-marketed item.

Regulations

- (4) For the purposes of paragraph (2)(b), on the day on which this section commences, the regulations may prescribe that 2 or more brands that are listed brands of a pharmaceutical item on that day are co-marketed brands of the pharmaceutical item.

84AF Responsible person for a brand of a pharmaceutical item

- (1) The Minister may, by legislative instrument, determine that a person is the responsible person for a brand of a pharmaceutical item if:
 - (a) the person notified the Minister that the person is or will be the supplier of the brand of the pharmaceutical item to:
-

- (i) wholesalers; or
 - (ii) in the case of a supply where wholesalers are not involved—approved pharmacists directly; and
 - (b) the brand of the pharmaceutical item is a listed brand; and
 - (c) there is no determination in force under this section that another person is the responsible person for:
 - (i) the brand of the pharmaceutical item; or
 - (ii) the brand of any other pharmaceutical item.
- (2) The notification referred to in paragraph (1)(a) may be made before or after the commencement of this section.

84AG Therapeutic groups

Determinations

- (1) The Minister may, by legislative instrument, determine:
 - (a) one or more therapeutic groups; and
 - (b) that 2 or more listed drugs are in the same therapeutic group.
- (1A) If the Minister proposes to make a determination under paragraph (1)(a), the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed determination.
- (2) A determination for the purposes of paragraph (1)(b) may specify the circumstances in which a listed drug is, or is not, in a therapeutic group.
- (3) In making a determination for the purposes of paragraph (1)(b), the Minister may have regard to advice (if any) given (whether before or after the commencement of this section) to the Minister by the Pharmaceutical Benefits Advisory Committee to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.
- (4) If:
 - (a) section 99ADH has applied to a brand of a pharmaceutical item; and
 - (b) the Minister has determined, under paragraph (1)(b), that the drug in the pharmaceutical item is in a therapeutic group;

the Minister must, by legislative instrument, vary the determination to remove the drug from that group with effect on the day that section 99ADH applied to the brand of the pharmaceutical item.

- (5) Without limiting the powers of the Minister under subsection (1), the Minister may, by legislative instrument, vary a determination to remove a drug from a therapeutic group that contains only 2 drugs. In that case, the group will contain only that remaining drug.

Regulations

- (6) On the day on which this section commences, the regulations may prescribe one or more therapeutic groups.

84AH Exempt items

The Minister may, by legislative instrument, determine that a pharmaceutical item (the *relevant item*) is an *exempt item* if:

- (a) there is only one listed brand of the relevant item; and
- (b) there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar to the listed brand of the relevant item; and
- (c) the relevant item and at least one listed brand of another pharmaceutical item have the same drug; and
- (d) the Minister is satisfied, having regard to advice (if any) given to the Minister by the Pharmaceutical Benefits Advisory Committee (whether before or after the commencement of this section), that:
 - (i) the listed drug in the relevant item represents suitable therapy for a particular patient population; and
 - (ii) the relevant item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item; and
 - (iii) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item.

84AI Rounding amounts

If an amount worked out under this Part is not a number of whole cents, round the amount to the nearest cent (rounding 0.5 cents upwards).

35 Paragraph 84C(3)(b)

Omit “the benefit referred to in the prescription”, substitute “upon the prescription, the pharmaceutical benefit or repatriation pharmaceutical benefit (the *benefit*)”.

36 Paragraph 84C(4)(c)

Omit “and the Commonwealth price for the pharmaceutical benefit exceeds \$28.60”, substitute “, the Commonwealth price for the pharmaceutical benefit exceeds \$28.60 and an approved pharmacist or approved medical practitioner is not entitled to be paid by the Commonwealth under subsection 99(2AA) an amount that is equal to the special patient contribution for a brand of a pharmaceutical item that is the pharmaceutical benefit”.

37 Paragraph 84C(4)(c)

Omit “in relation to the pharmaceutical benefit”, substitute “for the brand of the pharmaceutical item”.

38 Paragraph 84C(4)(d)

Omit “and the Commonwealth price for the pharmaceutical benefit exceeds \$4.60”, substitute “, the Commonwealth price for the pharmaceutical benefit exceeds \$4.60 and an approved pharmacist or approved medical practitioner is not entitled to be paid by the Commonwealth under subsection 99(2AA) an amount that is equal to the special patient contribution for a brand of a pharmaceutical item that is the pharmaceutical benefit”.

39 Paragraph 84C(4)(d)

Omit “in relation to the pharmaceutical benefit”, substitute “for the brand of the pharmaceutical item”.

40 Sub-subparagraph 84C(4)(e)(i)(A)

Omit “agreed price”, substitute “price worked out in accordance with a determination in force under subsection (7)”.

41 Subsection 84C(6)

Repeal the subsection.

42 Subsection 84C(7)

Omit “agreed”.

43 Paragraph 84C(8)(a)

Repeal the paragraph, substitute:

- (a) in the case of a pharmaceutical benefit that is a listed brand of a pharmaceutical item—take as a basis the approved price to pharmacists of the brand of the pharmaceutical item that was in force on the first day of the month of the year in which the supply occurs; and

44 At the end of paragraph 84C(8)(b)

Add “and”.

45 Subsection 84C(11) (definition of *approved price to pharmacists*)

Repeal the definition.

46 Subsection 84C(11) (definition of *ready-prepared pharmaceutical benefit*)

Repeal the definition.

47 Subsection 85(1)

Omit “the drugs and medicinal preparations in relation to which this Part applies”, substitute “pharmaceutical benefits”.

48 Subparagraphs 85(2)(a)(i), (a)(ii), (b)(i) and (b)(ii)

Omit “in writing”, substitute “by legislative instrument”.

49 Subsection 85(2A)

Omit “in a declaration under subsection (2)”, substitute “by legislative instrument”.

50 Paragraph 85(2A)(a)

Omit “declare”, substitute “determine”.

51 Paragraph 85(2A)(a)

Omit “specify”, substitute “determine”.

52 Subsections 85(2AA) and (2AB)

Repeal the subsections, substitute:

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

(2AB) If:

- (a) under subsection (2AA), the Minister proposes to revoke or vary a declaration under subsection (2) in relation to a drug or medicinal preparation; and
- (b) the drug or medicinal preparation would cease to be a listed drug on and after the day the revocation or variation comes into force;

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.

53 Subsections 85(2B), (2C) and (2D)

Repeal the subsections.

54 Subsection 85(3)

After “Minister may”, insert “, by legislative instrument,”.

55 Subsection 85(3)

Omit all the words after “forms of a”, substitute “listed drug”.

56 Subsection 85(4)

Omit “drug or medicinal preparation” (first occurring), substitute “listed drug”.

57 Subsection 85(4)

Omit “drug or medicinal preparation” (second occurring), substitute “drug”.

58 After subsection 85(4)

Insert:

- (5) The Minister may, by legislative instrument, determine the manner of administration of a form of a listed drug, being a form of the drug in relation to which a determination under subsection (3) is in force.

59 Subsection 85(6)

Repeal the subsection, substitute:

- (6) The Minister may, by legislative instrument, determine a brand of a pharmaceutical item.

60 Subsection 85(8)

Repeal the subsection.

61 Subsection 85A(1)

After “benefit”, insert “or pharmaceutical item”.

Note: The heading to section 85A is altered by inserting “**or pharmaceutical items**” after “**benefits**”.

62 Paragraph 85A(2)(a)

Repeal the paragraph, substitute:

- (a) determine the maximum quantity or number of units of:
 - (i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or
 - (ii) in any other case—the pharmaceutical benefit;that may, in one prescription, be directed to be supplied on any one occasion, either for all purposes or for particular purposes; and

63 After section 85A

Insert:

85AB Minister may determine that a listed drug is on F1 or F2

- (1) Subject to subsection (5), the Minister may, by legislative instrument, determine that a listed drug is on F1 or F2.
 - (2) The Minister may only determine that the drug is on F1 if the drug satisfies all the criteria for F1.
-

Note: For other circumstances in which the Minister may determine that a listed drug is on F1, see section 99AEJ.

- (3) The Minister may only determine that the drug is on F2 if the drug does not satisfy one or more of the criteria for F1.
- (4) The *criteria for F1* are as follows:
- (a) there are no brands of pharmaceutical items that:
 - (i) have the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the pharmaceutical items on any day in the relevant period;
 - (b) there are no brands of pharmaceutical items that:
 - (i) have another listed drug that is in the same therapeutic group as the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the pharmaceutical items on any day in the relevant period;
 - (c) the drug was not on F2 on the day before the determination under subsection (1) comes into force.
- (5) This section does not apply to the drug if:
- (a) the drug is in a combination item; and
 - (b) there are no brands of combination items that:
 - (i) have the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the combination items on any day in the relevant period.
- (6) In this section:
- relevant period* means the period that consists of:
- (a) the day before the day the determination under subsection (1) comes into force; and
 - (b) the day the determination under subsection (1) comes into force.

85AC Minister may determine that a listed drug is in Part A or Part T of F2

- (1) If, under section 85AB, the Minister determines that a drug is on F2, the Minister may, by legislative instrument, determine that the drug is in Part A or Part T of F2.
- (2) The Minister may only determine that the drug is in Part A if the drug satisfies neither of the criteria for Part T.
- (3) The Minister may only determine that the drug is in Part T if the drug satisfies either or both of the criteria for Part T.
- (4) The *criteria for Part T* are as follows:
 - (a) the drug is in the same therapeutic group as a drug that is in Part T;
 - (b) the drug was in Part T on the day before the determination under subsection (1) comes into force.
- (5) A determination under this section ceases to be in force on 1 January 2011.

85AD Price agreements

- (1) The Minister and the responsible person for a listed brand of a pharmaceutical item may, from time to time, agree, by reference to a quantity or number of units of the pharmaceutical item, an amount that is, for the purposes of this Part, taken to be the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists.

Note: Division 3A limits the Minister's power to agree to amounts for the purposes of subsection (1).

- (2) It does not matter that at the time the agreement is made:
 - (a) the person is not yet the responsible person; or
 - (b) the item is not yet a pharmaceutical item.However, the person must be the responsible person, and the item must be the pharmaceutical item, at the time the amount referred to in subsection (1) comes into force.
- (3) The agreement must be in writing.

64 Section 85B

Repeal the section, substitute:

85B Price determinations and special patient contributions

Section applies if no price agreement

- (1) This section applies if the Minister and the responsible person for a listed brand of a pharmaceutical item have been unable to make a price agreement for the brand of the pharmaceutical item.

Price determination

- (2) The Minister may, by legislative instrument, determine, by reference to a quantity or number of units of the pharmaceutical item, the amount that is, for the purposes of this Part, taken to be the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists.

Note: Division 3A limits the Minister's power to determine amounts under subsection (2).

Claimed price determination

- (3) The Minister may, by legislative instrument, determine, by reference to a quantity or number of units of the pharmaceutical item, the amount that is, for the purposes of this Part, taken to be the price claimed by the responsible person as the responsible person's price for sales of the brand of the pharmaceutical item to approved pharmacists.

Special patient contribution

- (4) The amount that is the **special patient contribution** for the brand of the pharmaceutical item is the difference between the responsible person's Commonwealth price for the brand of the pharmaceutical item and the Commonwealth price for the brand of the pharmaceutical item.
 - (5) If the Minister makes a determination under subsection (3), the Minister may, by legislative instrument, determine the circumstances in which the Commonwealth is to pay the special patient contribution for the brand of the pharmaceutical item.
 - (6) In this section:
-

Commonwealth price means the Commonwealth price in relation to the brand of the pharmaceutical item.

responsible person's Commonwealth price means the price that would have been the Commonwealth price in relation to the brand of the pharmaceutical item if that Commonwealth price had been based on the price determined by the Minister under subsection (3) to be the price claimed by the responsible person as the responsible person's price for sales of the brand of the pharmaceutical item.

65 Subsection 87(2AA)

Omit "agreed price referred to in section 84C", substitute "price worked out in accordance with a determination in force under subsection 84C(7)".

66 Subsection 87(2A)

Omit all the words after "pharmaceutical benefit", substitute "that is a listed brand of a pharmaceutical item and in relation to which a determination under section 85B is in force, charge the person to whom it is supplied an amount equal to the special patient contribution for the brand of the pharmaceutical item, unless the approved pharmacist or approved medical practitioner is entitled to be paid by the Commonwealth that special patient contribution under subsection 99(2AA)".

67 After subsection 88(1)

Insert:

- (1AA) When writing a prescription under subsection (1) for the supply of a pharmaceutical benefit that has a pharmaceutical item, the medical practitioner, in identifying the pharmaceutical benefit to be supplied, need not specify:
- (a) a listed brand of the pharmaceutical item in the pharmaceutical benefit; or
 - (b) the manner of administration of the pharmaceutical item in the pharmaceutical benefit.

68 After subsection 88(1A)

Insert:

- (1B) When writing a prescription under subsection (1A) for the supply of a pharmaceutical benefit that has a pharmaceutical item, the participating dental practitioner, in identifying the pharmaceutical benefit to be supplied, need not specify:
- (a) a listed brand of the pharmaceutical item in the pharmaceutical benefit; or
 - (b) the manner of administration of the pharmaceutical item in the pharmaceutical benefit.

69 Paragraph 88(5)(a)

Repeal the paragraph, substitute:

- (a) there be supplied on one occasion a quantity or number of units of:
 - (i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or
 - (ii) in any other case—the pharmaceutical benefit; in excess of the maximum quantity or number of units (if any) applicable under a determination of the Minister under subsection 85A(2); or

70 Subsection 88(6)

Omit all the words after “number of”, substitute:

units of:

- (a) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or
- (b) in any other case—the pharmaceutical benefit; not exceeding the total quantity or number of units that could be prescribed if the medical practitioner directed a repeated supply.

71 At the end of section 88

Add:

- (8) If, in one prescription:
 - (a) the supply of a pharmaceutical benefit (the *first benefit*) is directed by referring to a listed brand of a pharmaceutical item; and
 - (b) the supply of another pharmaceutical benefit (the *second benefit*) is directed by referring to another listed brand of the pharmaceutical item or a listed brand of another

pharmaceutical item that is bioequivalent or biosimilar to the brand of the pharmaceutical item;
then the prescription is taken to direct the repeated supply of the first benefit.

72 Section 88A

Omit “declared, in a declaration made under subsection 85(2)”, substitute “determined, under subsection 85(2A)”.

73 Section 88A

Omit “declaration pursuant to subsection 85(2A)”, substitute “determination under subsection 85(2A)”.

73A After section 98AA

Insert:

98AB Notification by Department of alterations to pharmaceutical benefits scheme

The Secretary must cause to be made publicly available on the Department’s website information on the outcomes of the changes to the pharmaceutical benefits scheme resulting from the introduction of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*.

74 Paragraph 98B(2)(a)

Repeal the paragraph, substitute:

- (a) in the case of a pharmaceutical benefit that is a listed brand of a pharmaceutical item—take as a basis the approved price to pharmacists of the brand of the pharmaceutical item that was in force on the first day of the month of the year in which the supply occurs; and

75 Subsection 98B(3) (definition of *approved price to pharmacists*)

Repeal the definition, substitute:

approved price to pharmacists of a listed brand of a pharmaceutical item means:

- (a) if a price agreement is in force in relation to the brand of the pharmaceutical item—the amount in force under the agreement as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists; or
- (b) if a price determination is in force in relation to the brand of the pharmaceutical item—the amount in force under the determination as the amount that is, for the purposes of this Part, taken to be the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists.

76 Subsection 98B(3) (definition of *ready-prepared pharmaceutical benefit*)

Repeal the definition.

77 Subsection 98B(3) (definition of *special pharmaceutical benefit*)

Repeal the definition.

78 Paragraph 99(2)(a)

After “for the”, insert “supply of the”.

79 After subsection 99(2)

Insert:

(2AA) If:

- (a) an approved pharmacist or approved medical practitioner is entitled to be paid an amount by the Commonwealth under subsection (2) in relation to the supply of a pharmaceutical benefit; and
- (b) a determination under subsection 85B(5) is in force in relation to a listed brand of a pharmaceutical item that is the pharmaceutical benefit; and
- (c) the brand of the pharmaceutical item was supplied in the circumstances specified in that determination;

then, subject to section 99AAA and the conditions determined under section 98C and applicable at the time of the supply, the approved pharmacist or approved medical practitioner is entitled to be paid by the Commonwealth an amount that is equal to the

amount of the special patient contribution for the brand of the pharmaceutical item.

80 Paragraphs 99(2AB)(c) and (2B)(c)

Omit “units of the pharmaceutical benefit that could, but for that subsection, have been directed to be supplied on any one occasion does not, at the time of the supply, exceed \$4.60;”, substitute:

units of:

- (i) if the pharmaceutical benefit has a pharmaceutical item—the pharmaceutical item; or
- (ii) in any other case—the pharmaceutical benefit; that could, apart from that subsection, have been directed to be supplied on any one occasion does not, at the time of the supply, exceed \$4.60;

81 After Division 3 of Part VII

Insert:

Division 3A—Price reductions

Subdivision A—Preliminary

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 that is not a combination item.

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

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

- (a) flowing on from the 12.5% price reduction required under Subdivision B; and

- | |
|---|
| <p>(b) arising if a pharmaceutical item has a drug on F2 on a particular day.</p> |
|---|

99ACA Definitions etc.

- (1) In this Division:

component drug, in relation to a drug in a combination item, means a drug or medicinal preparation that is contained in that drug.

listed component drug means a component drug in relation to which a declaration under subsection 85(2) is in force.

- (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 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 that section; 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.
- (3) The Minister may, by legislative instrument, determine that a 12.5% administrative price reduction has applied to a class of pharmaceutical items.

Subdivision B—12.5% price reductions for new brands of pharmaceutical items that are not combination items

99ACB 12.5% price reduction for new brands of pharmaceutical items that are not combination items

When section applies to new brands

- (1) Subject to subsections (2) and (3), this section applies to a brand (the *new brand*) of a pharmaceutical item (the *trigger item*) that is not a combination item if:
- (a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger item on a day (the *determination day*); and
 - (b) on the day before the determination day, the new brand of the trigger item was not a listed brand of the trigger item; and
 - (c) on the day before the determination day:
 - (i) a brand (the *existing brand*) of a pharmaceutical item (the *existing item*) was a listed brand of the existing item; and
 - (ii) the new brand of the trigger item is bioequivalent or biosimilar to the existing brand of the existing item; and
 - (iii) the trigger item and existing item have the same drug and manner of administration.

Note: For the purposes of paragraph (c), 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.

Circumstances in which section does not apply

- (2) This section does not apply in relation to the new brand of the trigger item if:
- (a) the trigger item is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied; or
 - (b) another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied; or
 - (c) if the drug that is in the trigger item is in a therapeutic group—a pharmaceutical item that:

- (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger item;
- is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied.
- (3) This section does not apply in relation to the new brand of the trigger item if:
- (a) any of the following has applied:
 - (i) subsection (1);
 - (ii) subsection 99ACF(1) or (2) because of item 1 of the table in that section;
- in relation to:
- (b) the new brand, or another listed brand, of the trigger item; or
 - (c) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new brand of the trigger item; or
 - (d) if the drug that is in the trigger item is in a therapeutic group—a listed brand of a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subparagraph (a)(i), subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEI.

12.5% price reduction

- (4) 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.
- (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 price to pharmacists, on the day before the determination day, of the existing brand of the existing item, reduced by 12.5%.

Apportioning if quantities different

- (6) If:
- (a) the approved price to pharmacists, on the day before the determination 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 (4), 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.

Section does not limit Minister's powers

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

Subdivision C—Price reductions for combination items

99ACC Price reductions for single brands of combination items

When section applies

- (1) This section applies if:
- (a) subsection 85AB(5) applies to the drug in a combination item; and
 - (b) there is only one listed brand (the *single brand*) of the combination item; and
 - (c) an agreed price (the *existing agreed price*) is in force for the single brand of the combination item; and
 - (d) after the day on which the existing agreed price came into force for the single brand of the combination item:
 - (i) if the drug in the combination item contains only one listed component drug—that listed component drug

- becomes subject to a statutory price reduction on a day (the *reduction day*); or
- (ii) if the drug in the combination item contains 2 or more listed component drugs—one of the listed component drugs becomes subject to a statutory price reduction on a day (the *reduction day*); or
 - (iii) if the drug in the combination item contains 2 or more listed component drugs—2 or more of the listed component drugs become subject to a statutory price reduction on the same day (the *reduction day*); and
- (e) on the reduction day, or on the day before that day, no listed brand of another combination item that has a drug that contains the same component drugs as the combination item:
- (i) is bioequivalent or biosimilar to the single brand of the combination item; and
 - (ii) has the same manner of administration as the single brand of the combination item.

Price reduction

- (2) The existing agreed price ceases to have effect at the end of the day before the reduction day.
- (3) The Minister may, under a price agreement, agree on a new price for the single brand of the combination item that comes into force on the reduction day.

Note: The new price for the single brand of the combination item may be the same as the existing agreed price.

- (4) If the Pharmaceutical Benefits Advisory Committee gives advice to the Minister under subsection 101(4AC) in relation to the combination item, then, in working out the new price of the single brand of the combination item, the Minister may have regard to that advice in considering the extent (if any) to which to reduce the existing agreed price.
- (4A) If:
- (a) subsection (4) applies; and
 - (b) the Minister decides to reduce the existing agreed price;
- then, in agreeing the new price of the single brand of the combination item, the Minister:

- (c) may have regard to the advice referred to in subsection (4) in relation to the combination item; and
 - (d) must take into account, in relation to the listed component drug, or each listed component drug, that became subject to statutory price reduction:
 - (i) the approved price to pharmacists, 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.
- (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, in relation to the listed component drug, or each listed component drug, that became subject to statutory price reduction:
- (a) the approved price to pharmacists, on the reduction day, of each brand of a pharmaceutical item that has the drug that is the listed component drug; and
 - (b) the quantity of the listed component drug contained in the combination item.

Section does not limit Minister's powers

- (5) This section does not limit the Minister's powers, after the reduction day, to make further price agreements in relation to the single brand of the combination item.

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 any of the following has applied to a listed brand of a pharmaceutical item that has a drug that is the listed component drug:
 - (a) section 99ACB;
 - (b) subsection 99ACF(1) or (2) because of any of the items in the table in that section;
 - (c) section 99ADH.

99ACD 12.5% price reduction for new brands of combination items

When section applies to new brands

- (1) Subject to subsections (2) and (3), this section applies to a brand (the ***new brand***) of a pharmaceutical item (the ***trigger combination item***) that is a combination item if:
- (a) a determination under subsection 85(6) comes into force in relation to the new brand of the trigger combination item on a day (the ***determination day***); and
 - (b) on the day before the determination day, the new brand of the trigger combination item was not a listed brand of the trigger combination item; and
 - (c) on the day before the determination day:
 - (i) a brand (the ***existing brand***) of a pharmaceutical item (the ***existing item***) was a listed brand of the existing item; and
 - (ii) the new brand of the trigger combination item is bioequivalent or biosimilar to the existing brand of the existing item; and
 - (iii) the drug in the trigger combination item and existing item contain the same component drugs; and
 - (iv) the trigger combination item and the existing item have the same manner of administration.

Note: For the purposes of paragraph (c), the new brand and the existing brand may be the same brand, or the trigger combination item and the existing item may be the same pharmaceutical item.

Circumstances in which section does not apply to new brands

- (1A) This section does not apply in relation to the new brand of the trigger combination item if:
- (a) the trigger combination item is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied; or
 - (b) another combination item that has the same drug and manner of administration as the new brand of the trigger combination item is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied; or
 - (c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:

- (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item;
- is in a class of pharmaceutical items to which a 12.5% administrative price reduction has applied.
- (2) This section does not apply in relation to the new brand of the trigger combination item if subsection (1) or section 99ACE has applied in relation to:
 - (a) the new brand, or another listed brand, of the trigger combination item; or
 - (b) a brand of another combination item that:
 - (i) has a drug that contains the same component drugs as the new brand of the trigger combination item; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item; or
 - (c) if the drug in the trigger combination item is in a therapeutic group—a combination item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger combination item.

Note: For the purposes of this subsection, subsection (1) is taken not to have applied in relation to a brand of a pharmaceutical item in some cases: see section 99AEL.

12.5% price reduction

- (4) The Minister:
 - (a) may, under a price agreement, agree an agreed price for the new brand of the trigger combination item that comes into force on the determination day; and
 - (b) must not make a determination under section 85B for the new brand of the trigger combination item.
- (5) Subject to subsections (6) and (7), the agreed price of the new brand of the trigger combination item must not exceed the approved price to pharmacists, on the day before the determination day, of the existing brand of the existing item, reduced by 12.5%.
- (6) If, on a day before the determination day:

- (a) one or more of the listed component drugs contained in the drug in the existing item had been subject to a 12.5% price reduction; and
- (b) because of that price reduction, 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 extent to which the 12.5% price reduction was taken into account in working out the amount of the reduction to the approved price to pharmacists; and
- (d) the quantity of the listed component drug contained in the drug in the existing item.

Apportioning if quantities different

(7) If:

- (a) the approved price to pharmacists, on the day before the determination 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 combination item is not for the same quantity or number of units;

then, for the purposes of subsection (4), 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 new trigger item.

Section does not limit Minister's powers

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

99ACE Flow-on of 12.5% price reduction to related brands of combination items

When section applies

- (1) This section applies if:
 - (a) section 99ACD has applied to a brand (the *new brand*) of a combination item (the *new combination item*); and
 - (b) the new agreed price for the new brand of the combination item comes into force on a day (the *reduction day*); and
 - (c) on that day, a price agreement or a determination under section 85B is in force in relation to any of the following listed brands (the *related brand*) of a combination item (the *related item*):
 - (i) another listed brand of the new combination item;
 - (ii) a brand of another combination item that has a drug that contains the same component drugs as the new brand of the new combination item and that has the same manner of administration as the new brand of the new combination item;
 - (iii) if the drug in the new combination item is in a therapeutic group—a combination item that has another drug that is in that group and has the same manner of administration as the new brand of the new combination item; and
 - (d) the related item is not an exempt item.

Note: For the purposes of paragraph (c), the new brand and the related brand may be the same brand, or the new combination item and the related item may be the same pharmaceutical item.

12.5% price reduction

- (2) The approved price to pharmacists of the related brand of the related item ceases to be in force at the end of the day before the reduction day. The claimed price (if any) for the related brand of the related item ceases to be in force at the end of the day before the reduction day.
- (3) If a price agreement was in force on the day before the reduction day for the related brand of the related item, the Minister may:
 - (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 subsection (5), does not exceed the agreed price in force, on the day before that day, for the related brand of the related item, reduced by 12.5%; or
 - (b) in a determination under section 85B for the related brand of the related item, specify a determined price that:
 - (i) comes into force on the reduction day; and
 - (ii) subject to subsection (5), does not exceed the agreed price in force, on the day before that day, for the related brand of the related item, reduced by 12.5%.
- (4) If a determination under section 85B was in force for the related brand of a related item on the day before the reduction day, the Minister may:
- (a) in a determination under section 85B for the related brand of the related item, specify a determined price and a claimed price for the related brand of the related item that:
 - (i) come into force on the reduction day; and
 - (ii) subject to subsection (5), do not exceed those respective prices in force on the day before that day, reduced by 12.5%; or
 - (b) in a price agreement for the related brand of the related item, 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 subsection (5), does not exceed the determined price in force, on the day before that day, for the related brand, reduced by 12.5%.
- (5) If, on a day before the reduction day:
- (a) one or more of the listed component drugs contained in the drug in the related item had been subject to a 12.5% price reduction; and
 - (b) because of that price reduction, 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 extent to which the 12.5% price reduction was taken into account in working out the amount of the reduction to the approved price to pharmacists; and
- (d) the quantity of the listed component drug contained in the drug in the related item.

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) further determinations under section 85B;for the related brand of the related item.

Subdivision D—Other statutory price reductions

99ACF Statutory price reductions

Reduction equal to percentage or amount

- (1) Subject to section 99ACG, if:
 - (a) a section referred to in column 2 of the table in this subsection applies to a listed brand of a pharmaceutical item on a day specified in the section (the **reduction day**); and
 - (b) subsection (2) does not apply to the listed brand of the pharmaceutical item on the reduction day; and
 - (c) on the day before the reduction day, an agreed price was, or a determined price and a claimed price were, in force for the listed brand of the pharmaceutical item;then, the agreed price is, or the determined price and the claimed price are, taken to be reduced, on the reduction day, by the following:
 - (d) the percentage specified in column 3 of the table for the section referred to in column 2;
 - (e) if there is a staged percentage for the listed brand of the pharmaceutical item for the reduction day—the amount specified in column 3 of the table for the section referred to in column 2.

Statutory price reductions table

Item	Section	Percentage or amount for section
1	99ACH	12.5%
2	99ACI	2%
3	99ACJ	25%
4	99ACK	the amount that equals the staged percentage for the listed brand of the pharmaceutical item for the reduction day

Note: Subsection (1) does not apply if there is no determination under subsection 85(6) in respect of the pharmaceutical item in force on the specified day (whether or not the determination was revoked following a request by the responsible person for the pharmaceutical item).

Reduction more than percentage or amount

- (2) This subsection applies if:
- (a) a section referred to in column 2 of the table in subsection (1) applies to a listed brand of a pharmaceutical item on a reduction day; and
 - (b) on the reduction day the approved price to pharmacists of the listed brand of the pharmaceutical item does not exceed the approved price to pharmacists of the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than:
 - (i) the percentage specified in column 3 of the table for the section referred to in column 2; or
 - (ii) if there is a staged percentage for the listed brand of the pharmaceutical item for the reduction day—the amount specified in column 3 of the table for the section referred to in column 2; and
 - (c) if a determination under section 85B was in force in relation to the listed brand of the pharmaceutical item on the day before the reduction day and on the reduction day—the claimed price for the brand of the pharmaceutical item does not exceed the claimed price for the brand of the pharmaceutical item in force on the day before the reduction day, reduced by more than the percentage or amount specified in column 3 of the table for the section referred to in column 2.
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Sequence of application of 2 or more price reductions

- (3) If 2 or more items of the table in subsection (1) apply to a listed brand of a pharmaceutical item on the same day:
- (a) apply the items in the order they appear in the table; and
 - (b) apply the second and later items as if the determined price and the claimed price, or the agreed price, (as the case requires) were those prices as affected by the operation of the item or items that have already been applied.

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) further determinations under section 85B;
- for the listed brand of the pharmaceutical item.

Definitions

- (5) In this section:

staged percentage means the percentage prescribed for the purposes of paragraph 99ACK(3)(b).

99ACG Other price reductions do not apply if 12.5% statutory price reduction or price disclosure reduction applies

12.5% and 2% reductions

- (1) If:
- (a) any of the following applies to a listed brand of a pharmaceutical item on 1 April or 1 August in a year:
 - (i) section 99ACB;
 - (ii) section 99ACD or 99ACE;
 - (iii) subsection 99ACF(1) or (2) because of item 1 of the table in that section; and
 - (b) apart from this subsection, item 2 of the table would apply in relation to the brand of the pharmaceutical item, or another listed brand of the pharmaceutical item, on 1 August in that year;

item 2 of the table does not apply on 1 August in that year in relation to the brand of the pharmaceutical item or the other brand of the pharmaceutical item.

Price disclosure reductions and other price reductions

(2) If:

- (a) section 99ADH has applied to a listed brand of a pharmaceutical item (the *first item*) on a day; and
- (b) apart from this subsection, any of the following provisions would apply on or after that day to a listed brand of a pharmaceutical item that has the same drug and manner of administration as the first item:
 - (i) section 99ACB;
 - (ii) section 99ACD or 99ACE;
 - (iii) subsection 99ACF(1) or (2) because of any item of the table in that section;

then none of the provisions mentioned in paragraph (b) apply, on or after that day, to:

- (c) the first item; or
- (d) a listed brand of the pharmaceutical item that has the same drug and manner of administration as the first item.

99ACH 12.5% statutory price reduction flow-on to related brands

(1) If:

- (a) section 99ACB has applied to the agreed price for a brand (the *new brand*) of a pharmaceutical item (the *new item*); and
- (b) that price comes into force on a day (the *reduction day*); and
- (c) on the reduction day, 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
- (d) the related item is not a combination item; and
- (e) the related item is not an exempt item;

then this section applies to the related brand of the related item on the reduction day.

(2) For the purposes of paragraph (1)(c), a related brand of a related item is any of the following:

- (a) another listed brand of the new item;
- (b) a listed brand of another pharmaceutical item that has the same drug and manner of administration as the new item;
- (c) if the drug in the new item is in a therapeutic group—a listed brand of a pharmaceutical item that:
 - (i) has another drug that is in that group; and
 - (ii) has the same manner of administration as the new brand of the trigger item.

Note: For the purposes of subsection (2), the new brand and the related brand may be the same brand, and the new item and the related item may be the same pharmaceutical item.

99ACI 2% statutory price reduction

- (1) If:
 - (a) on the day before a 2% price reduction day, a price agreement or a determination under section 85B is in force in relation to a listed brand of a pharmaceutical item; and
 - (b) the drug in the pharmaceutical item is in Part A of F2 on the 2% price reduction day; and
 - (c) the pharmaceutical item is not an exempt item on the 2% price reduction day;

this section applies to the listed brand of the pharmaceutical item on the 2% price reduction day.

Note: Section 99ACG may affect the operation of this section.

- (2) In this section, each of the following is a **2% price reduction day**:
 - (a) 1 August 2008;
 - (b) 1 August 2009;
 - (c) 1 August 2010.

99ACJ 25% statutory price reduction on single day

- (1) If:
 - (a) on 31 July 2008, a price agreement or a determination under section 85B is in force in relation to a listed brand of a pharmaceutical item that is not a prescribed brand of that item; and
 - (b) the drug in the pharmaceutical item is in Part T of F2 on 1 August 2008; and

(c) the pharmaceutical item is not an exempt item on 1 August 2008;

this section applies to the listed brand of the pharmaceutical item on 1 August 2008.

(2) In this section:

prescribed brand means a brand of a pharmaceutical item prescribed for the purposes of subsection 99ACK(2).

99ACK 25% statutory price reduction phased over 2 or more days

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

- (a) on the day before that day, a price agreement or a determination under section 85B is in force in relation to the brand of the pharmaceutical item; and
- (b) the drug in the pharmaceutical item is in Part T of F2 on 1 August 2008; and
- (c) the pharmaceutical item is not an exempt item on the reduction day.

(2) The regulations may prescribe, for the purposes of this Division, a listed brand of a pharmaceutical item.

(3) For each brand of a pharmaceutical item prescribed under subsection (2), the regulations may prescribe:

- (a) 2 or more reduction days; and
- (b) for a reduction day:
 - (i) a percentage of the determined price, or agreed price, in force in relation to the brand of the pharmaceutical item on 31 July 2008; and
 - (ii) if a determination under section 85B was in force in relation to the brand of the pharmaceutical item on the day before the reduction day concerned and on the reduction day concerned—a percentage of the claimed price in force in relation to the brand of the pharmaceutical item on the day before the reduction day concerned.

(4) The percentages prescribed for each brand of the pharmaceutical item must not total more than 25%.

Division 3B—Price disclosure

Subdivision A—Preliminary

99AD What this Division is about

This Division requires the responsible person for certain brands of pharmaceutical items to comply with the price disclosure requirements for each supply of those brands of pharmaceutical items.

- Subdivision B has the price disclosure requirements. It provides for regulations to set out the kind of information that is required to be provided for the brand of the pharmaceutical item, the form and manner in which that information is to be provided and when that information is to be provided.
- 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.
- Subdivision D provides for the consequences of failing to comply with the price disclosure requirements.

In addition, this Division reduces the approved price to pharmacists of the brand of the pharmaceutical item in specified circumstances (see Subdivision E). This reduction happens as a result of the price being adjusted based on information collected about brands of pharmaceutical items.

99ADA Application of this Division

- (1) On and after the commencement of this section, this Division applies to brands of pharmaceutical items that have drugs in Part A of F2.
- (2) On and after 1 January 2011, this Division applies to all brands of pharmaceutical items that have drugs on F2.

- (3) This Division does not apply to brands of pharmaceutical items that are exempt items.

99ADB Definitions etc.

- (1) In this Division:

adjusted approved ex-manufacturer price of a brand of a pharmaceutical item is the amount equal to the amount of the weighted average disclosed price of the brand of the pharmaceutical item.

adjusted approved price to pharmacists of a brand of a pharmaceutical item is the amount worked out in accordance with regulations made under subsection (2).

approved ex-manufacturer price of a brand of a pharmaceutical item is the amount worked out in accordance with regulations made under subsection (3).

price disclosure requirements has the meaning given by section 99ADC.

weighted average disclosed price of a brand of a pharmaceutical item is the weighted average disclosed price of the brand of the pharmaceutical item determined by the Minister under subsection (4) or (5).

Adjusted approved price to pharmacists

- (2) For the purposes of the definition of *adjusted approved price to pharmacists* in subsection (1), the regulations may, by reference to the adjusted approved ex-manufacturer price of a brand of a pharmaceutical item, prescribe a method or formula for working out the adjusted approved price to pharmacists of the brand of the pharmaceutical item.

Approved ex-manufacturer price

- (3) For the purposes of the definition of *approved ex-manufacturer price* in subsection (1), the regulations may, by reference to the approved price to pharmacists of a brand of a pharmaceutical item, prescribe a method or formula for working out the approved ex-manufacturer price of the brand of the pharmaceutical item.

Weighted average disclosed price

- (4) The Minister may, by legislative instrument, determine the weighted average disclosed price of a brand of a pharmaceutical item in accordance with the regulations.
- (5) If the Minister makes a determination under subsection (4) in relation to a brand of a pharmaceutical item (the *first item*), the Minister must, by legislative instrument, determine, in accordance with the regulations, the weighted average disclosed price of every brand of every pharmaceutical item that has the same drug and manner of administration as the first item.
- (6) Without limiting subsection (4) or (5), the regulations may prescribe a method or formula for determining the weighted average disclosed price of a brand of a pharmaceutical item. The method or formula prescribed may take into account information (if any) that has been provided in compliance with the price disclosure requirements, and any other information, about:
 - (a) the brand of the pharmaceutical item; and
 - (b) other brands of the pharmaceutical item; and
 - (c) all brands (including the brand) of all pharmaceutical items that have the same drug and manner of administration as the pharmaceutical item.

Subdivision B—Price disclosure requirements

99ADC The price disclosure requirements

- (1) The *price disclosure requirements* for a supply of a brand of a pharmaceutical item are:
 - (a) to provide information prescribed by the regulations in relation to the supply of the brand of the pharmaceutical item by the responsible person to a person or entity prescribed by the regulations; and
 - (b) to provide that information in the manner and form prescribed by the regulations; and
 - (c) to provide that information at the times prescribed by the regulations.
 - (2) Without limiting subsection (1), the regulations may prescribe information relating to:
-

- (a) the price of the brand of the pharmaceutical item supplied, which may be by reference to the quantity or number of units of the pharmaceutical item supplied; and
- (b) the volume of the supply; and
- (c) the person to whom the supply was made; and
- (d) when the supply was made; and
- (e) the type and value of any benefit (whether monetary or otherwise) provided to persons by the responsible person in relation to the supply, whether or not the benefit also relates to another supply of a product (the **related product**) that is:
 - (i) the brand of the pharmaceutical item; or
 - (ii) any other pharmaceutical item available in the brand or any other brand; or
 - (iii) any other product; and
- (f) if the benefit referred to in paragraph (e) also relates to a supply of the related product—information relating to the supply of the related product (including the price and volume of the supply); and
- (g) any other matter that is relevant in determining the weighted average disclosed price of the brand of the pharmaceutical item.

Subdivision C—When the price disclosure requirements apply

99ADD Mandatory compliance with the price disclosure requirements

Main case: listing of a new brand of a pharmaceutical item

- (1) A person is required to comply with the price disclosure requirements for each supply of a brand (the **mandatory brand**) of a pharmaceutical item (the **mandatory item**) if:
 - (a) the person is the responsible person for the mandatory brand of the mandatory item; and
 - (b) a determination under subsection 85(6) comes into force in relation to the mandatory brand of the mandatory item on a day (the **determination day**); and
 - (c) on the day before the determination day, the mandatory brand was not a listed brand of the mandatory item; and
 - (d) on the determination day, or on the day before that day:

- (i) a brand (the *existing brand*) of a pharmaceutical item (the *existing item*) is a listed brand of the existing item; and
- (ii) the mandatory brand of the mandatory item is bioequivalent or biosimilar to the existing brand of the existing item; and
- (iii) the mandatory item and existing item have the same drug and manner of administration.

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

Flow-on case: effect of listing the mandatory brand on related brands

- (2) A person who is required under subsection (1) to comply with the price disclosure requirements for each supply of the mandatory brand of the mandatory item is also required to comply with the price disclosure requirements for each supply of every brand (the *related brands*) of every pharmaceutical item (the *related items*) if:
 - (a) the person is the responsible person for the related brands of the related items; and
 - (b) on the determination day, the related brands are listed brands of the related items; and
 - (c) the mandatory item and related items have the same drug and manner of administration.

Note: The related brands may include the mandatory brand, and the related items may include the mandatory item.

When the price disclosure requirements start to apply

- (3) The person is required to comply with the price disclosure requirements under subsections (1) and (2) on and after the determination day.

99ADE Voluntary compliance with the price disclosure requirements

- (1) A person may elect, in writing, to be required to comply with the price disclosure requirements for each supply of every brand (the *volunteered brands*) of every pharmaceutical item (the *volunteered items*) if:

- (a) the person is the responsible person for the volunteered brands of the volunteered items; and
 - (b) another person is required under subsection 99ADD(1) to comply with the price disclosure requirements for each supply of the mandatory brand of the mandatory item; and
 - (c) the volunteered brands are listed brands of the volunteered items on the determination day (see paragraph 99ADD(1)(b)); and
 - (d) the mandatory item and volunteered items have the same drug and manner of administration.
- (2) If the person makes the election, the person is required, on and after the day the election is made, to comply with the price disclosure requirements for each supply of the volunteered brands of the volunteered items.
- (3) If the person makes the election, the person must give a copy of the election to the Minister within 7 days after the day the election is made.
- (4) If the person does not do so by the end of that period, then, on the day after the end of that period, the election is taken never to have been made.
- (5) The person cannot revoke the election.

Note: For the cases where the election may be taken to be revoked, see section 99AEL.

Subdivision D—Consequences for failing to comply with the price disclosure requirements

99ADF Offence for failing to comply with the price disclosure requirements

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

Penalty: 60 penalty units.

- (2) Subsection 4K(2) of the *Crimes Act 1914*, which creates daily or continuing offences, does not apply to an offence against subsection (1).

99ADG Other consequences for failing to comply with the price disclosure requirements

- (1) This section applies if:
- (a) a responsible person is required to comply with the price disclosure requirements for a supply of a brand (the ***disclosure brand***) of a pharmaceutical item (the ***disclosure item***); and
 - (b) the responsible person does not comply with those requirements for the supply of the disclosure brand of the disclosure item.
- (2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:
- (a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the disclosure brand of the disclosure item;
 - (b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:
 - (i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or
 - (ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or
 - (iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.

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

- (3) Without limiting the powers of the Minister under subsection (2), in exercising a power under that subsection, the Minister may have regard to:
- (a) the number of times the responsible person did not comply with the price disclosure requirements for:
 - (i) the disclosure brand of the disclosure item; and
 - (ii) if, in addition to the disclosure brand of the disclosure item, the person was also required to comply with the price disclosure requirements for a brand of a pharmaceutical item—the brand of the pharmaceutical item; and
 - (b) the period in which the non-compliances occurred; and
 - (c) the duration of each non-compliance; and
 - (d) the reasons for the non-compliances; and
 - (e) whether those reasons are, in the Minister’s opinion, reasonable; and
 - (f) any other matter the Minister thinks is relevant.
- Note: For the purposes of subparagraph (a)(ii), a brand mentioned in that subparagraph may be the disclosure brand, or a pharmaceutical item mentioned in that subparagraph may be the disclosure item.
- (4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Subdivision E—Price reduction

99ADH Price reduction based on information provided under the price disclosure requirements

When this section applies

- (1) This section applies if:
- (a) under section 99ADB, the Minister determines the weighted average disclosed price of a brand of a pharmaceutical item; and
 - (b) a price agreement or price determination is in force in relation to the brand of the pharmaceutical item; and
 - (c) the weighted average disclosed price of the brand of the pharmaceutical item is at least 10% less than the approved ex-manufacturer price of the brand of the pharmaceutical item; and
-

- (d) the Minister gives the responsible person for the brand of the pharmaceutical item a notice stating:
 - (i) the adjusted approved ex-manufacturer price of the brand of the pharmaceutical item; and
 - (ii) the adjusted approved price to pharmacists of the brand of the pharmaceutical item; and
 - (iii) the day (the *reduction day*) the adjusted approved price to pharmacists of the brand of the pharmaceutical item comes into force for the purposes of the price agreement or price determination.
- (2) For the purposes of subparagraph (1)(d)(iii), the reduction day must be:
 - (a) a prescribed day; and
 - (b) a day that is not before the latest of the following days:
 - (i) the day that is 6 months after the day the notice is given;
 - (ii) if the day is before 1 January 2011 and the drug in the pharmaceutical item is in Part A of F2—1 August 2009;
 - (iii) if the day is on or after 1 January 2011 and the drug in the pharmaceutical item was not in Part T of F2 on 31 December 2010—1 January 2011;
 - (iv) if the day is on or after 1 January 2011 and the drug in the pharmaceutical item was in Part T of F2 on 31 December 2010—1 August 2012.

Price reduction

- (3) If, on the reduction day, the approved price to pharmacists of the brand of the pharmaceutical item would, apart from this section, be higher than the adjusted approved price to pharmacists of the brand of the pharmaceutical item, then, on the reduction day, the amount of the approved price to pharmacists is taken to be reduced to the amount of the adjusted approved price to pharmacists for the purposes of the price agreement or price determination.

Claimed price reduction

- (4) If, on the reduction day:
 - (a) a determination under subsection 85B(3) is in force in relation to the brand of the pharmaceutical item; and

(b) the approved price to pharmacists of the brand of the pharmaceutical item is reduced because of subsection (3); then, for the purposes of that determination, on the reduction day the claimed price for the brand of the pharmaceutical item is taken to be reduced by the percentage worked out as follows:

$$\frac{AAP - AAAP}{AAP} \times 100$$

where:

AAAP means the adjusted approved price to pharmacists of the brand of the pharmaceutical item.

AAP means the approved price to pharmacists of the brand of the pharmaceutical item.

Section not to limit Minister's powers

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

Notice is not a legislative instrument

- (6) A notice under paragraph (1)(d) is not a legislative instrument.

Division 3C—Guarantee of supply

Subdivision A—Preliminary

99AE What this Division is about

This Division is about guaranteeing the supply of certain brands of pharmaceutical items.

Subdivision B requires the responsible person for certain brands of pharmaceutical items to supply those brands of pharmaceutical items during a specified period.

Subdivision C sets out which brands of pharmaceutical items are required to be supplied, and the period in which they are required to be supplied.

Subdivision D provides for when the responsible person is considered to have failed to supply, or been unable to supply, the brand of the pharmaceutical item.

Subdivision E requires the responsible person to notify the Minister if the person will fail or be unable to supply, or has failed or been unable to supply, the brand of the pharmaceutical item.

Subdivision F sets out the possible consequences for the responsible person if the person fails, or is unable, to supply the brand of the pharmaceutical item.

Subdivision G sets out the possible consequences for other brands of pharmaceutical items that were affected by the brand of the pharmaceutical item, if the brand of the pharmaceutical item is delisted under Subdivision F.

99AEA Definitions

In this Division:

fails to supply has the meaning given by section 99AEE.

guaranteed brand of a guaranteed item has the meaning given by sections 99AEC and 99AED.

guaranteed period, for a guaranteed brand of a guaranteed item, has the meaning given by:

- (a) if the guaranteed brand of the guaranteed item is a brand of a pharmaceutical item to which subsection 99AEC(2) applies—subsection 99AEC(3); or
- (b) if the guaranteed brand of the guaranteed item is a brand of a pharmaceutical item to which subsection 99AED(2) applies—subsection 99AED(3).

unable to supply has the meaning given by section 99AEF.

Subdivision B—Guarantee of supply

99AEB Guarantee of supply

The responsible person for a guaranteed brand of a guaranteed item must supply the guaranteed brand of the guaranteed item during the guaranteed period for the guaranteed brand of the guaranteed item.

Note 1: For the circumstances when a responsible person fails to supply, or is unable to supply, in the guaranteed period, see sections 99AEE and 99AEF.

Note 2: For the consequences for the responsible person for failing to supply, or being unable to supply, in the guaranteed period, see Subdivision F.

Subdivision C—Brands that are guaranteed brands

99AEC Guaranteed brand: new brand

- (1) A brand of a pharmaceutical item is a *guaranteed brand of a guaranteed item* for the purposes of this Division (other than section 99AED) if subsection (2) applies to the brand of the pharmaceutical item.
- (2) This subsection applies to a brand (the *guaranteed brand*) of a pharmaceutical item (the *guaranteed item*) if:
 - (a) a determination under subsection 85(6) comes into force in relation to the guaranteed brand of the guaranteed item on a day (the *determination day*); and
 - (b) on the day before the determination day, the guaranteed brand was not a listed brand of the guaranteed item; and
 - (c) on the determination day, or on the day before that day:
 - (i) a brand (the *existing brand*) of a pharmaceutical item (the *existing item*) is a listed brand of the existing item; and
 - (ii) the guaranteed brand of the guaranteed item is bioequivalent or biosimilar to the existing brand of the existing item; and
 - (iii) the guaranteed item and the existing item have the same drug and manner of administration.

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

Guaranteed period

- (3) The **guaranteed period** for the guaranteed brand of the guaranteed item is the period that commences on the determination day and ends on the earliest of the following days:
- (a) the last day of the 24 month period beginning on the determination day;
 - (b) if, after the determination day:
 - (i) a determination under subsection 85(6) comes into force on a day (the **later determination day**) in relation to a brand (the **later brand**) of a pharmaceutical item (the **later item**); and
 - (ii) the later brand of the later item is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item; and
 - (iii) on the day before the later determination day, the later brand was not a listed brand of the later item;the later determination day;
 - (c) if, after the determination day, subsection 99AED(2) applies to:
 - (i) a brand of the guaranteed item; or
 - (ii) a brand of a pharmaceutical item that is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item;the new price day referred to in paragraph 99AED(2)(d);
 - (d) the day that is the first whole day on which the guaranteed brand is not a listed brand of the guaranteed item.

Note 1: For the purposes of paragraph (b), the later brand and the guaranteed brand may be the same brand, or the later item and the guaranteed item may be the same item.

Note 2: For the purposes of paragraph (c), the brand mentioned in that paragraph and the guaranteed brand may be the same brand, or the pharmaceutical item mentioned in that paragraph and the guaranteed item may be the same pharmaceutical item.

99AED Guaranteed brand: first brand to offer a lower price

- (1) A brand of a pharmaceutical item is a **guaranteed brand of a guaranteed item** for the purposes of this Division (other than section 99AEC) if subsection (2) applies to the brand of the pharmaceutical item.

- (2) This subsection applies to a brand (the **guaranteed brand**) of a pharmaceutical item (the **guaranteed item**) if:
- (a) the drug in the guaranteed item is on F2; and
 - (b) the guaranteed brand is a listed brand of the guaranteed item; and
 - (c) the Minister and the responsible person for the guaranteed brand of the guaranteed item agree, in a price agreement, an agreed price (the **new price**) of the guaranteed brand of the guaranteed item; and
 - (d) on the day (the **new price day**) the new price comes into force, the new price is less than what the approved price to pharmacists of the guaranteed brand of the guaranteed item would have been on that day if the new price had not come into force; and
 - (e) the responsible person was the first responsible person for a brand of the guaranteed item to offer the Minister the new price.

Guaranteed period

- (3) The **guaranteed period** for the guaranteed brand of the guaranteed item is the period that commences on the new price day and ends on the earliest of the following days:
- (a) the last day of the 24 month period beginning on the new price day;
 - (b) if, after the new price day:
 - (i) a determination under subsection 85(6) comes into force on a day (the **later determination day**) in relation to a brand (the **later brand**) of a pharmaceutical item (the **later item**); and
 - (ii) the later brand of the later item is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item; and
 - (iii) on the day before the later determination day, the later brand was not a listed brand of the later item;the later determination day;
 - (c) if, after the new price day, subsection (2) applies, in another application of that subsection, to:
 - (i) a brand of the guaranteed item; or

- (ii) a brand of a pharmaceutical item that is bioequivalent or biosimilar to the guaranteed brand of the guaranteed item;

the day the new price referred to in that subsection under the other application comes into force;

- (d) the day that is the first whole day on which the guaranteed brand is not a listed brand of the guaranteed item.

Note 1: For the purposes of paragraph (b), the later brand and the guaranteed brand may be the same brand, or the later item and the guaranteed item may be the same item.

Note 2: For the purposes of paragraph (c), the brand mentioned in that paragraph and the guaranteed brand may be the same brand, or the pharmaceutical item mentioned in that paragraph and the guaranteed item may be the same pharmaceutical item.

Subdivision D—Meaning of fails to supply and unable to supply

99AEE Meaning of *fails to supply*

- (1) A responsible person for a guaranteed brand of a guaranteed item ***fails to supply*** the guaranteed brand of the guaranteed item if:
 - (a) a wholesaler or an approved pharmacist requests the responsible person to supply the wholesaler or pharmacist with an amount of the guaranteed brand of the guaranteed item; and
 - (b) the responsible person fails to supply that amount to the wholesaler or pharmacist within:
 - (i) a reasonable period; or
 - (ii) if the regulations prescribe a period—that period; after receiving the request.
- (2) The responsible person fails to supply the guaranteed brand of the guaranteed item on the day after the end of that period.

99AEF Meaning of *unable to supply*

A responsible person for a guaranteed brand of the guaranteed item is ***unable to supply*** the guaranteed brand of the guaranteed item on a day if the responsible person would be unable to supply any amount of the guaranteed brand of the guaranteed item within a reasonable period of being requested by a wholesaler or an

approved pharmacist, on that day, to supply the guaranteed brand of the guaranteed item.

Subdivision E—Requirement to notify Minister of failure or inability to supply etc.

99AEG Requirement to notify Minister of failure to supply etc.

Notification of belief that responsible person will fail to supply or be unable to supply

- (1) If, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item forms the belief that the person will fail to supply, or will be unable to supply, the guaranteed brand of the guaranteed item in the period, then, as soon as practicable after the person forms the belief, the person must notify the Minister, in writing, of that belief.

Notification of failure to supply or inability to supply

- (2) If, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item fails to supply, or is unable to supply, the guaranteed brand of the guaranteed item, then, as soon as practicable after the failure or inability occurs, the person must notify the Minister, in writing, of that failure or inability unless the person notified the Minister about that supply under subsection (1).

Offence

- (3) A person commits an offence if:
 - (a) the person is required to notify the Minister under subsection (1) or (2); and
 - (b) the person fails to do so.

Penalty: 60 penalty units.

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

Subdivision F—Consequences for guaranteed brands of failure or inability to supply

99AEH Minister’s powers if responsible person fails to supply, or is unable to supply, guaranteed brand

- (1) This section applies if, during the guaranteed period for a guaranteed brand of a guaranteed item, the responsible person for the guaranteed brand of the guaranteed item fails to supply, or is unable to supply, the guaranteed brand of the guaranteed item on one or more occasions.
 - (2) Without limiting any power the Minister may otherwise have under this Part, the Minister may do any or all of the following:
 - (a) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to the guaranteed brand of the guaranteed item;
 - (b) by legislative instrument, revoke or vary a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (c) refuse to make a determination under subsection 85(6) in relation to any brand of any pharmaceutical item of the responsible person;
 - (d) if the only listed brand of a pharmaceutical item would be a brand of the pharmaceutical item of the responsible person—refuse to make:
 - (i) a declaration under subsection 85(2) in relation to the drug in the pharmaceutical item; or
 - (ii) a determination under subsection 85(3) in relation to the form of the pharmaceutical item; or
 - (iii) a determination under subsection 85(5) in relation to the manner of administration of the pharmaceutical item.
- Note: For the purposes of paragraphs (b), (c) and (d), a brand mentioned in those paragraphs may be the guaranteed brand, or a pharmaceutical item mentioned in those paragraphs may be the guaranteed item.
- (3) Without limiting the powers of the Minister under subsection (2), in exercising a power under that subsection, the Minister may have regard to:
 - (a) the number of times the responsible person failed to supply, or was unable to supply:

- (i) the guaranteed brand of the guaranteed item; and
 - (ii) if, in addition to the guaranteed brand of the guaranteed item, the person was also required to supply other guaranteed brands of guaranteed items—those other guaranteed brands of guaranteed items; and
 - (b) the period in which those failures or inabilities occurred; and
 - (c) the duration of those failures or inabilities; and
 - (d) the reasons for those failures or inabilities; and
 - (e) whether those reasons are, in the Minister’s opinion, reasonable; and
 - (f) any other matter the Minister thinks is relevant.
- (4) The refusals referred to in paragraphs (2)(c) and (d) are not legislative instruments.

Subdivision G—Consequences for other brands

99AEI Minister may increase approved price to pharmacists etc. if guaranteed brand delisted

- (1) This section applies if, under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the *delisted brand*) of a pharmaceutical item (the *existing item*).
- (2) Without limiting any power the Minister may otherwise have under this Part, the Minister may:
 - (a) under section 85AD, make or vary a price agreement to increase the agreed price; or
 - (b) under section 85B, make or vary a determination to increase the determined price and the claimed price;for a brand of a pharmaceutical item that has an approved price to pharmacists that was reduced because the delisted brand of the existing item was:
 - (c) the new brand of the trigger item referred to in section 99ACB; or
 - (d) the new brand of the trigger combination item referred to in section 99ACD; or
 - (e) the guaranteed brand of the guaranteed item under subsection 99AED(2).

- (3) If the Minister exercises the power referred to in subsection (2), then the Minister may, by legislative instrument, determine that:
- (a) if subsection 99ACB(1) applied to the delisted brand of the existing item—for the purposes of subsection 99ACB(3), subsection 99ACB(1) is taken not to have applied to the delisted brand of the existing item; or
 - (b) if subsection 99ACD(1) applied to the delisted brand of the existing item—for the purposes of subsection 99ACD(2), subsection 99ACD(1) is taken not to have applied to the delisted brand of the existing item.
- (4) If the Minister makes a determination under subsection (3), the determination has effect on the day specified in the determination, being a day on or after the determination comes into force.

99AEJ Minister may determine drug is on F1 if guaranteed brand delisted

The Minister may, by legislative instrument, determine that a listed drug is on F1 if:

- (a) under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the *delisted brand*) of a pharmaceutical item (the *existing item*); and
- (b) before the revocation or variation came into force, subsection 99AEC(2) applied to the delisted brand of the existing item; and
- (c) after the revocation or variation comes into force, there is only one listed brand of a pharmaceutical item (the *remaining item*) that is bioequivalent or biosimilar to the delisted brand of the existing item; and
- (d) apart from paragraph 85AB(4)(c), the drug in the remaining item satisfies the criteria for F1 referred to in subsection 85AB(4); and
- (e) the drug in the remaining item was on F1 on the day before subsection 99AEC(2) began to apply to the delisted brand of the existing item.

99AEK Minister may revoke or vary formulary determination if guaranteed brand delisted

Without limiting the power of the Minister under section 85AB, the Minister may, by legislative instrument, revoke or vary a determination under section 85AB if:

- (a) under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the *delisted brand*) of a pharmaceutical item (the *existing item*); and
- (b) before the revocation or variation came into force, subsection 99AEC(2) applied to the delisted brand of the existing item; and
- (c) after the revocation or variation comes into force, there is only one listed brand of a pharmaceutical item (the *remaining item*) that is bioequivalent or biosimilar to the delisted brand of the existing item; and
- (d) the remaining item is a combination item; and
- (e) the drug in the remaining item was not on F1 or F2 on the day before subsection 99AEC(2) began to apply to the delisted brand of the existing item.

99AEL Minister may determine price disclosure election is revoked if guaranteed brand delisted

- (1) This section applies if:
 - (a) under section 99AEH, the Minister revokes or varies a determination under subsection 85(6) in relation to a brand (the *delisted brand*) of a pharmaceutical item (the *existing item*); and
 - (b) the delisted brand of the existing item was the mandatory brand of the mandatory item referred to in section 99ADD; and
 - (c) other brands (the *volunteered brands*) of pharmaceutical items (the *volunteered items*) were the volunteered brands of the volunteered items referred to in section 99ADE in the application of that section resulting from the delisted brand of the existing item being the mandatory brand of the mandatory item; and
 - (d) the responsible person for the volunteered brands of the volunteered items made an election under section 99ADE in
-

relation to the volunteered brands of the volunteered items;
and

- (e) when the responsible person made the election:
 - (i) the responsible person was not required to comply with the price disclosure requirements under Division 3B for the volunteered brands of the volunteered items; and
 - (ii) the responsible person could not, because of an application of section 99ADE resulting from a brand of pharmaceutical item (other than the delisted brand of the existing item) being the mandatory brand of the mandatory item, have made an election under that section in relation to the volunteered brands of the volunteered items; and
- (f) that election is in force; and
- (g) the responsible person requests the Minister to determine that the election is revoked.

(2) The Minister may determine that the election is revoked.

(3) If the Minister makes a determination under subsection (2), the election is taken to have been revoked on the day specified in the determination, being a day that is on or after the day the determination comes into force.

(4) A determination under subsection (2) is not a legislative instrument.

82 After subsection 101(3B)

Insert:

- (3BA) If the Committee is of the opinion that a drug or medicinal preparation should be made available as a pharmaceutical benefit under this Part, the Committee must, in its recommendation under subsection (3), specify whether the drug or medicinal preparation and another drug or medicinal preparation should be treated as interchangeable on an individual patient basis.

83 After subsection 101(4A)

Insert:

Function relating to Minister's determination of therapeutic groups

- (4AA) If the Committee is of the opinion that the Minister should, or should not, determine a therapeutic group, the Committee must advise the Minister accordingly.

Function relating to Minister's determination about exempt items

- (4AB) If the Committee is of the opinion that the following circumstances exist in relation to a pharmaceutical item:
- (a) the listed drug in the pharmaceutical item represents suitable therapy for a particular patient population;
 - (b) the pharmaceutical item is suitable for use by a particular subgroup of that population because of either or both of the form and manner of administration of the drug in the item;
 - (c) no other pharmaceutical item that has that drug is suitable for use by that subgroup because of either or both of the form and manner of administration of the drug in that other item;
- the Committee must advise the Minister that those circumstances exist in relation to the pharmaceutical item.

Function relating to Minister's decisions about prices of combination items

- (4AC) If the Committee is satisfied that therapy involving a combination item provides, for some patients:
- (a) a significant improvement in patient compliance with the therapy; or
 - (b) a significant improvement in efficacy or reduction in toxicity;
- over alternative therapies, then the Committee must advise the Minister accordingly.

84 Subsection 103(2A)

Omit “the pharmaceutical benefit specified in a prescription (the *specified benefit*), another pharmaceutical benefit (the *substitute benefit*) that is marketed under a different brand from the specified benefit”, substitute “a listed brand of a pharmaceutical item specified in a prescription (the *specified benefit*), another listed brand of the pharmaceutical item (the *substitute benefit*)”.

85 Paragraph 103(2A)(c)

Repeal the paragraph.

86 Paragraph 103(2A)(d)

Omit “under that brand”.

87 Subsection 103(4)

After “prescription for”, insert “the supply of”.

88 Subsection 103(4)

After “with the pharmaceutical benefit”, insert “supplied”.

89 Subsection 103(4AA)

After “benefit” (wherever occurring), substitute “or pharmaceutical item”.

90 Subsection 103(4AC)

After “benefit” (first and second occurring), insert “or pharmaceutical item”.

91 Subsection 103(4AC) (definition of *MQ*)

After “benefit” (wherever occurring), insert “or pharmaceutical item”.

92 Subsection 103(4AC) (definition of *RA*)

After “the pharmaceutical benefit”, insert “, or a pharmaceutical benefit that has the pharmaceutical item,”.

93 Paragraphs 103(4AD)(a) and (b)

After “benefit”, insert “or pharmaceutical item”.

93A After section 104A

Insert:

104B Report on impact of *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*

(1) The Minister must prepare a report on:

- (a) the impact of the reforms made by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*; and

- (b) the impact on the cost of pharmaceutical benefits to patients as a consequence of the reforms.
- (2) The preparation of the report must be completed by 31 December 2009.
- (3) The Minister must cause a copy of the report to be laid before each House of the Parliament within 5 sitting days of that House after the day of the completion of the preparation of the report.

Part 2—Application, saving and transitional provisions

94 Transitional provision—determination under subsection 84C(7) of the *National Health Act 1953*

A determination in force immediately before the commencement of this Schedule under subsection 84C(7) of the *National Health Act 1953* is taken to have been made under that subsection as in force immediately after that commencement.

95 Application of amendments to section 85 of the *National Health Act 1953*

The amendments made by this Schedule to section 85 of the *National Health Act 1953* apply to declarations or determinations under that section that come into force on and after the commencement of this Schedule.

96 Transitional provision—determinations under subsection 85(6) of the *National Health Act 1953*

- (1) This item applies if, on the day before this Schedule commences, a determination (the *brand determination*) under subsection 85(6) of the *National Health Act 1953* was in force in relation to a drug or medicinal preparation (the *drug*) in a form in relation to which a declaration under subsection 85(2), and a determination under subsection 85(3), of that Act was in force on that day.
- (2) The brand determination is taken to have been in force on that day in relation to a pharmaceutical item that has the drug in that form for the purposes of the following:
 - (aa) subsections 85AB(4) and (5);
 - (a) subsections 99ACB(1), (5) and (6);
 - (b) subsection 99ACC(1);
 - (c) subsections 99ACD(1), (5) and (7);
 - (d) subsections 99ACE(2), (3) and (4);
 - (e) subsections 99ACF(1) and (2);
 - (f) subsection 99ADD(1);
 - (g) subsection 99AEC(2).

- (3) If the determination day or reduction day referred to in subsection 99ACB(1), 99ACC(1), 99ACD(1), 99ADD(1) or 99AEC(2) is the day this Schedule commences, then:
- (a) subparagraphs 99ACC(1)(e)(ii) and 99ACD(1)(c)(iv) are to be disregarded; and
 - (b) subparagraphs 99ACB(1)(c)(iii), 99ADD(1)(d)(iii) and 99AEC(2)(c)(iii) are to be disregarded to the extent that they refer to the manner of administration of a pharmaceutical item.

97 Application of amendments relating to prescriptions

The amendments made by this Schedule that insert subsections 4(2), 84(1B), 88(1AA), 88(1B) and 88(8) of the *National Health Act 1953* apply to prescriptions written on and after the commencement of this Schedule.

98 Application of amendments to section 84AAA of the *National Health Act 1953*

The amendments made by this Schedule to section 84AAA of the *National Health Act 1953* apply in relation to supplies made on or after the commencement of this Schedule of pharmaceutical benefits that have pharmaceutical items that are specified in a legislative instrument made under that section on or after the commencement of this Schedule.

99 Transitional provision—approved price to pharmacists, agreed price, determined price and claimed price

Approved price to pharmacists

- (1) If the determination day or reduction day referred to in subsection 99ACB(5) or (6), 99ACD(5) or (7), 99ACE(2) or 99ACF(2) of the *National Health Act 1953* is the day this Schedule commences, then the reference in those subsections to the approved price to pharmacists on the day (the **relevant day**) before the determination day or reduction day is a reference to the approved price to pharmacists within the meaning of subsection 98B(3) of that Act as in force on the relevant day.

Agreed price

- (2) If the reduction day referred to in subsection 99ACC(2), 99ACE(3) or 99ACF(1) of the *National Health Act 1953* is the day this Schedule commences, then the reference in those subsections to the agreed price

on the day (the *relevant day*) before the determination day or reduction day is a reference to the amount that is:

- (a) referred to in paragraph (a) of the definition of *approved price to pharmacists* in subsection 98B(3) of that Act as in force on the relevant day; and
- (b) in force on the relevant day.

Determined price

- (3) If the reduction day referred to in subsection 99ACE(4) or 99ACF(1) of the *National Health Act 1953* is the day this Schedule commences, then the reference in those subsections to the determined price on the day before the reduction day is a reference to the amount that is:
 - (a) specified in a determination under paragraph 85B(1)(d) of that Act as in force on the day before the reduction day; and
 - (b) in force on the day before the reduction day.

Claimed price

- (4) If the reduction day referred to in subsection 99ACE(2), 99ACE(4), 99ACF(1) or 99ACF(2) of the *National Health Act 1953* is the day this Schedule commences, then the reference in those subsections to the claimed price on the day before the reduction day is a reference to the amount that is:
 - (a) specified in a determination under paragraph 85B(1)(e) of that Act as in force on the day before the reduction day; and
 - (b) in force on the day before the reduction day.

99A Transitional provision—approved price to pharmacists

If the determination day or reduction day referred to in subsection 99ACD(6) or 99ACE(5) of the *National Health Act 1953* is a day that is on or after this Schedule commences, then the reference in those subsections to the approved price to pharmacists on a day (the *relevant day*) before the determination day or reduction day is a reference to the approved price to pharmacists within the meaning of subsection 98B(3) of that Act as in force on the relevant day.

100 Transitional provision—agreements under section 98B

An agreement:

- (a) referred to in paragraph (a) of the definition of *approved price to pharmacists* in subsection 98B(3) of the *National*
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Health Act 1953 as in force immediately before the commencement of this Schedule; and

(b) that is in force immediately before that commencement; continues in force, and may be dealt with, as if it had been made under section 85AD of that Act as inserted by this Schedule.

[*Minister's second reading speech made in—
House of Representatives on 24 May 2007
Senate on 12 June 2007*]

(97/07)
