



National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015

Select Legislative Instrument No. 163, 2015

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation.

Dated 17 September 2015

Peter Cosgrove
Governor-General

By His Excellency's Command

Sussan Ley
Minister for Health

OPC61080 - A

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1 Name

This is the *National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015*.

2 Commencement

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

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	19 September 2015
2. Schedule 1, items 1 and 2	1 January 2016.	1 January 2016
3. Schedule 1, items 3 and 4	1 May 2016.	1 May 2016
4. Schedule 1, items 5 and 6	The day after this instrument is registered.	19 September 2015
5. Schedule 1, item 7	1 May 2016.	1 May 2016
6. Schedule 1, items 8 to 16	The day after this instrument is registered.	19 September 2015

Note: This table relates only to the provisions of this instrument as originally made.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

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

No. 163, 2015

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3 Authority

This instrument is made under the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceutical Benefits) Regulations 1960

1 Paragraph 25(3)(a)

Omit all the words after “pharmaceutical benefit,”, substitute:

another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit or another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit:

- (i) in the period specified under subsection 84AAA(2) of the Act for the pharmaceutical benefit immediately preceding the day on which it is to be supplied to the person; or
- (ii) if no period is so specified—in the period of 20 days immediately preceding the day on which it is to be supplied to the person; or

2 Paragraph 25(4)(a)

Omit all the words after “pharmaceutical benefit,”, substitute:

another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit or another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit:

- (i) in the period specified under subsection 84AAA(2) of the Act for the pharmaceutical benefit immediately preceding the day on which it is to be supplied to the person; or
- (ii) if no period is so specified—in the period of 4 days immediately preceding the day on which it is to be supplied to the person; or

3 Subregulation 37F(3) (note)

Omit “Note”, substitute “Note 1”.

4 At the end of subregulation 37F(3)

Add:

Note 2: Subdivision 2A prescribes information that must not be taken into account in determining a weighted average disclosed price.

5 At the end of regulation 37S

Add:

- (4) This regulation has effect subject to regulation 37SA.

6 At the end of Subdivision 2 of Division 2 of Part 6A

Add:

37SA When weighted average disclosed price is the same as the applicable approved ex-manufacturer price

Despite regulation 37S, if all of the following apply, the *weighted average disclosed price* of the listed brand of the pharmaceutical item for the data collection period is taken to be the amount of the applicable approved ex-manufacturer price of the listed brand of the pharmaceutical item:

- (a) the total adjusted volume worked out for brands of the pharmaceutical item under regulation 37N:
 - (i) is more than zero; and
 - (ii) is no more than 10% of the sum of the total adjusted volumes for the brands of each pharmaceutical item with the same drug and manner of administration as the listed brand (including the pharmaceutical item of the listed brand);
- (b) the weighted average percentage difference worked out for brands of the pharmaceutical item under regulation 37P is not more than 3%;
- (c) there is not a related brand of the listed brand of the pharmaceutical item:
 - (i) that is bioequivalent or biosimilar to the listed brand of the pharmaceutical item; and
 - (ii) to which paragraphs (a) and (b) do not apply;
- (d) the Pharmaceutical Benefits Advisory Committee has not advised the Minister that the pharmaceutical item does not provide a significant improvement in efficacy or a reduction in toxicity over alternative therapies.

7 After Subdivision 2 of Division 2 of Part 6A

Insert:

Subdivision 2A—Information that must not be taken into account**37SB Information that must not be taken into account**

- (1) This Subdivision is made for subsection 99ADB(6A) of the Act.
- (2) Regulation 37SC prescribes information that must not be taken into account in determining the weighted average disclosed price of a listed brand of a pharmaceutical item (the *WADP brand*) in respect of a data collection period.
- (3) However, regulation 37SC does not apply in relation to determining a weighted average disclosed price for the purposes of regulation 37SA.
- (4) To avoid doubt, this Subdivision has effect:
 - (a) despite Subdivision 2 (weighted average disclosed price); and
 - (b) even if the information relates to the WADP brand.

37SC Originator brands

- (1) Information provided under regulation 37T about an originator brand must not be taken into account if:
 - (a) on the first day of each calendar month in the data collection period (from its beginning in relation to the originator brand) on which the originator brand is a listed brand, there is another listed brand of pharmaceutical item that:
 - (i) is not an originator brand; but
 - (ii) has the same pharmaceutical item as the originator brand; and
 - (b) at the end of the previous data collection period, the drug in the WADP brand had been on F2 for at least 30 months; and
 - (c) on a day at least 30 months before the end of the previous data collection period:
 - (i) there was a related brand of the WADP brand that had the same pharmaceutical item as, or was bioequivalent or biosimilar to, the WADP brand; or

- (ii) there were 2 or more related brands of the WADP brand that had the same pharmaceutical item as, or were bioequivalent or biosimilar to, each other.
- (2) Paragraph (1)(a) has effect even if the other listed brand is different from month to month.
- (3) However, subregulation (1) does not apply if taking the information into account would result in a higher weighted average percentage difference under regulation 37R (weighted average percentage difference for the WADP brand and all related brands).

8 Regulation 38 (definition of *Chairperson*)

Omit “appointed under regulation 39”, substitute “of the Pharmaceutical Benefits Advisory Committee”.

9 Regulation 38

Insert:

Deputy Chairperson means the Deputy Chairperson of the Pharmaceutical Benefits Advisory Committee.

10 Subregulation 38A(1)

Repeal the subregulation, substitute:

- (1) For paragraph 100B(1AA)(a) of the Act, the following industry organisations are prescribed:
 - (a) Medicines Australia Limited;
 - (b) Generic Medicines Industry Association Pty Ltd trading as the Generic and Biosimilar Medicines Association;
 - (c) Ausbiotech Ltd.
- (1A) For paragraph 100B(1AB)(a) of the Act, the following consumer organisations are prescribed:
 - (a) the Consumers Health Forum of Australia Ltd;
 - (b) the Australian Federation of AIDS Organisations Incorporated;
 - (c) the Australian Consumers’ Association.

11 Paragraph 38A(4)(c)

Repeal the paragraph.

12 Regulation 38B

Omit “subsection 100B(1A)”, substitute “subsection 100B(1AA), (1AB) or (1A)”.

13 Regulations 39 to 41

Repeal the regulations, substitute:

40 Resignation

A member may resign by notice in writing given to the Minister.

41 Presiding member

- (1) The Chairperson must preside at a meeting if the Chairperson is present.
- (2) If the Chairperson is absent and there is a Deputy Chairperson present, the Deputy Chairperson must preside at the meeting.
- (3) If:
 - (a) the Chairperson is absent; and
 - (b) there is no Deputy Chairperson present;the members attending the meeting must elect a member to preside at the meeting.

14 Subregulations 42(1) to (3)

Repeal the subregulations, substitute:

- (1) The Chairperson may, at any time, by notice in writing to all members, convene a meeting of the Committee.

15 Regulations 44 and 45

Repeal the regulations, substitute:

44 Voting

- (1) At a meeting of the Committee, the members present each have a deliberative vote.
- (2) A matter requiring a decision at a meeting must be determined by a majority of the votes of the members present and voting.

- (3) If an equal number of votes is cast for and against a matter at a meeting:
 - (a) the member presiding at the meeting may exercise a casting vote; and
 - (b) if that member declines to exercise a casting vote—the matter is resolved in the negative.
- (4) Decisions of the Committee must be recorded in the minutes of the meeting.

45 Disclosure of pecuniary interests by members

- (1) Each member must tell the Minister in writing, as soon as practicable after the beginning of each financial year, of all direct or indirect pecuniary interests that the member has, or proposes to acquire, in a business or in a body corporate carrying on a business that could conflict with the member's duties.
- (2) If a member does not have an interest of the kind mentioned in subregulation (1), the member must give a statement to that effect to the Minister.
- (3) If the member presiding at a meeting has a direct or indirect pecuniary interest in a matter that is to be considered at the meeting, the presiding member:
 - (a) must disclose the interest to the other members present at the meeting; and
 - (b) must not take part in the meeting during the consideration of that matter unless the other members present at the meeting agree that the presiding member may take part in the meeting.
- (4) If the presiding member is precluded from taking part in a meeting or part of a meeting because of paragraph (3)(b):
 - (a) if the presiding member is the Chairperson and a Deputy Chairperson is present—the Deputy Chairperson must act in the place of the Chairperson for the duration of the Committee's consideration of the matter; or
 - (b) if:
 - (i) the presiding member is the Chairperson and no Deputy Chairperson is present; or
 - (ii) the Deputy Chairperson is the presiding member;

the other members attending the meeting must elect a member who is present to act in the place of the presiding member for the duration of the Committee's consideration of the matter.

- (5) If a member (other than the presiding member) has a direct or indirect pecuniary interest in a matter that is to be considered at a meeting, the member:
- (a) must disclose the interest to the presiding member at the commencement of the meeting; and
 - (b) must not take part in the meeting during the consideration of that matter unless the presiding member allows the member to take part in the meeting.
- (6) The following matters must be recorded in the minutes of a meeting:
- (a) a disclosure made under subregulation (3) or (5);
 - (b) an agreement under paragraph (3)(b);
 - (c) consent of the presiding member under paragraph (5)(b).

16 At the end of Part 8

Add:

Division 5—Provisions for the National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015

62 Application

The amendments made by items 5 and 6 of Schedule 1 to the *National Health (Pharmaceutical Benefits) Amendment (2015 Measures No. 1) Regulation 2015* do not apply in relation to a data collection period that ends before 30 September 2015.