



National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014

Select Legislative Instrument No. 60, 2014

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 29 May 2014

Peter Cosgrove
Governor-General

By His Excellency's Command

Peter Dutton
Minister for Health

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1 Name of regulation

This regulation is the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*.

2 Commencement

This regulation commences on the day after it is registered.

3 Authority

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

4 Schedule(s)

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

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National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014

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Schedule 1—Amendments

National Health (Pharmaceutical Benefits) Regulations 1960

1 Subregulation 5(1)

Insert:

data collection period, for a brand of a pharmaceutical item: see regulation 37C.

delisted brand, of a pharmaceutical item: a listed brand of a pharmaceutical item becomes a delisted brand when a determination made under subsection 85(6) of the Act is no longer in force for that brand.

final day, in relation to a data collection period, means the last day of the data collection period.

incentive, for a brand of a pharmaceutical item, includes anything given as an incentive to take supply of the brand (including a delisted brand before it was delisted) whether the incentive is given:

- (a) before the supply of the brand, but on condition of taking supply; or
- (b) at, or after, the time of the supply of the brand; or
- (c) over a period of time; or
- (d) directly for the brand; or
- (e) indirectly for the brand (for a group of brands of pharmaceutical items or other products, for example).

initial month, for a brand of a pharmaceutical item that was not a listed brand immediately before the brand's start day, means the first month of the brand's first data collection period.

last listed brand, of a pharmaceutical item, means the brand of the pharmaceutical item that was the last to become a delisted brand before the final day.

price adjustment means an adjustment under:

- (a) a price agreement; or
- (b) a price determination; or

(c) Division 3A of Part VII of the Act.

price sampling day: see regulation 37D.

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

Note: For the definition of *exempt item*, see subsection 84(1) of the Act.

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

2 Part 6A (heading)

Repeal the heading, substitute:

Part 6A—Price reduction and price disclosure

3 Division 1 of Part 6A

Repeal the Division, substitute:

Division 1—Price reduction

37A Reduction day

For paragraph 99ADH(2)(b) of the Act, 1 August and 1 December in any year are prescribed.

4 Division 1A of Part 6A (heading)

Repeal the heading.

5 Divisions 2 to 4 of Part 6A

Repeal the Divisions, substitute:

Division 2—Price disclosure

Subdivision 1—Interpretation

37C Meaning of *data collection period*

Start of first data collection period

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

End of first data collection period

- (2) If, on the day before the start day for the brand (the *starting brand*) the price disclosure requirements apply to a related brand of the starting brand, the starting brand's first *data collection period* ends when the data collection period for any of the related brands ends.
- (3) Otherwise, the starting brand's first *data collection period* ends on:
 - (a) if the start day occurs between 2 April and 1 October—the next 31 March; or
 - (b) if the start day occurs between 2 October and 1 April—the next 30 September.

Start and end of subsequent data collection periods

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

Example 1: If a brand to which subregulation (2) applies has a start day of 1 July 2014, and the data collection period for a related brand ends on 30 September 2014:

- (a) the first data collection period starts on 1 July 2014; and
- (b) the first data collection period ends on 30 September 2014; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2014, 1 April 2015, 1 October 2015 and so on.

Example 2: If a brand to which subregulation (3) applies has a start day of 1 August 2014:

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- (a) the first data collection period starts on 1 August 2014; and
 - (b) the first data collection period ends on 31 March 2015; and
 - (c) subsequent data collection periods will be the 6 month periods that start on 1 April 2015, 1 October 2015, 1 April 2016 and so on.

Example 3: If a brand to which subregulation (3) applies has a start day of 1 December 2014:

- (a) the first data collection period starts on 1 December 2014; and
- (b) the first data collection period ends on 30 September 2015; and
- (c) subsequent data collection periods will be the 6 month periods that start on 1 October 2015, 1 April 2016, 1 October 2016 and so on.

37D Meaning of *price sampling day*

A day is a *price sampling day* for a data collection period for a brand of a pharmaceutical item if the day:

- (a) is the first day of a calendar month; and
- (b) the day is within whichever of the following periods commenced earlier:
 - (i) the data collection period;
 - (ii) the data collection period for another brand of the same pharmaceutical item.

37E Special rules for certain listed brands

- (1) Subregulations (3), (4) and (5) apply to a listed brand of a pharmaceutical item if:
 - (a) paragraphs 99ADB(3B)(a) and (b) of the Act apply to the listed brand; and
 - (b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.
- (2) Subregulations (4) and (5) apply to a listed brand of a pharmaceutical item if:
 - (a) the start day for the listed brand is the relevant day; and
 - (b) a weighted average disclosed price does not exist for another listed brand of the same pharmaceutical item for the data collection period.

Approved ex-manufacturer price on relevant day

- (3) For paragraph 99ADB(3B)(c) of the Act, the approved ex-manufacturer price of the listed brand of the pharmaceutical item on the relevant day is the approved ex-manufacturer price of the brand on the start day minus any amount that would have been added, and plus any amount that would have been deducted, because of a price adjustment, had the brand been a listed brand in the period:
- (a) starting on the relevant day; and
 - (b) ending immediately before the brand's start day.

Deemed data collection period and approved ex-manufacturer price for determining weighted average disclosed price

- (4) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision 2, the brand is taken to have had a data collection period:
- (a) beginning on the earliest day on which the data collection period began for any related brand of the listed brand; and
 - (b) ending on the day before the relevant day.
- (5) For the purpose of determining the weighted average disclosed price of the listed brand under Subdivision 2, the approved ex-manufacturer price of the listed brand on a price sampling day is taken to have been the approved ex-manufacturer price of the listed brand on the brand's start day minus any amount that would have been added, and plus any amount that would have been deducted, because of a price adjustment, had the brand been a listed brand in the period:
- (a) starting on the price sampling day; and
 - (b) ending immediately before the brand's start day.

Note: This enables an average approved ex-manufacturer price to be worked out for the purpose of determining the weighted average disclosed price.

Subdivision 2—Weighted average disclosed price

37F Method for determining weighted average disclosed price of listed brand of pharmaceutical item

- (1) This Subdivision is made for subsection 99ADB(6) of the Act.
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- (2) Regulations 37G to 37S prescribe the method for determining the weighted average disclosed price of a listed brand of a pharmaceutical item in respect of a data collection period for the listed brand.
 - (3) When using the method, the Minister may disregard information provided under regulation 37T for a data collection period if the information is incomplete.

Note: Section 99ADA of the Act provides that Division 3B (Price disclosure) of Part VII of the Act does not apply to brands of exempt items.

37G Step 1—Net revenue for brand

- (1) Work out the net revenue for the listed brand of the pharmaceutical item for the data collection period for the brand.
- (2) The *net revenue* is the revenue from sales of the listed brand for the data collection period, other than for the listed brand's initial month, minus the value of any incentive given in relation to sales of the listed brand for the data collection period, other than for the listed brand's initial month.

37H Step 2—Adjusted volume for brand

- (1) Work out the adjusted volume of the listed brand of the pharmaceutical item sold for the data collection period for the brand.
- (2) The *adjusted volume* is the number of packs of the listed brand sold for the data collection period, other than for the listed brand's initial month, worked out as if the size of the pack equals the pricing quantity of the listed brand on the final day.

Note: For the definition of *pricing quantity*, see subsection 84AK(1) of the Act.

37J Step 3—Average approved ex-manufacturer price for brand

- (1) Work out the average approved ex-manufacturer price of the listed brand of the pharmaceutical item for the data collection period for the brand.

- (2) The **average approved ex-manufacturer price** is the amount worked out by:
- (a) adding together, for each price sampling day for the listed brand for the data collection period:
 - (i) if the listed brand had an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price; or
 - (ii) if the listed brand did not have an approved ex-manufacturer price on the price sampling day—the approved ex-manufacturer price of a listed brand of the same pharmaceutical item; and
 - (b) dividing that amount by the number of price sampling days for the listed brand for the data collection period.

Note: A price sampling day may be within the data collection period for another brand of the same pharmaceutical item (see regulation 37D).

Adjustment for variation in pricing quantity

- (3) If the pricing quantity of a brand on a price sampling day is different from the pricing quantity of the brand on the final day, for the purposes of subregulation (2) the approved ex-manufacturer price of the brand on the price sampling day is taken to be:

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

where:

AEMP means the approved ex-manufacturer price of the brand on the price sampling day (for the pricing quantity of the brand on the price sampling day).

PQ1 means the pricing quantity of the brand on the price sampling day.

PQ2 means the pricing quantity of the brand on the final day.

37K Step 4—Disclosed price for brand

- (1) Work out the disclosed price of the listed brand of the pharmaceutical item for the data collection period for the brand.
- (2) The **disclosed price** is:

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- (a) if the adjusted volume (see step 2) of the listed brand is zero or less—zero; or
 - (b) if the adjusted volume (see step 2) of the listed brand is more than zero:
 - (i) the amount worked out by dividing the net revenue for the listed brand (see step 1) by the adjusted volume; or
 - (ii) if the amount worked out under subparagraph (i) is more than the average approved ex-manufacturer price for the listed brand for the data collection period—the average approved ex-manufacturer price of the listed brand.

37L Step 5—Price percentage difference of brand

- (1) Work out the price percentage difference of the listed brand of the pharmaceutical item for the data collection period.
- (2) The *price percentage difference* of the listed brand is the amount (expressed as a percentage to 2 decimal places) worked out as follows:
 - (a) subtract the listed brand's disclosed price for the data collection period (see step 4) from the listed brand's average approved ex-manufacturer price for the data collection period (see step 3); and
 - (b) divide that amount by the listed brand's average approved ex-manufacturer price for the data collection period.

37M Step 6—Repeat steps for each brand of pharmaceutical item

- (1) For each other brand of the same pharmaceutical item (including delisted brands) work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.
- (2) The price percentage difference of the other brand is worked out using steps 1 to 5, reading references to the listed brand as references to the other brand.
- (3) If the other brand of the pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:

- (a) if there is a listed brand of the same pharmaceutical item on the final day—the pricing quantity of the listed brand; or
- (b) if there is no listed brand of the same pharmaceutical item on the final day—the pricing quantity of the last listed brand immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

37N Step 7—Total adjusted volume of brands of pharmaceutical item

- (1) Work out the total adjusted volume of the brands of the pharmaceutical item.
- (2) The *total adjusted volume* is the amount worked out by adding together the adjusted volume for each brand of the pharmaceutical item for the brand's data collection period.

37P Step 8—Weighted average percentage difference of brands of pharmaceutical item

- (1) Work out the weighted average percentage difference of the brands of the pharmaceutical item.
- (2) The *weighted average percentage difference* is:
 - (a) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is zero or less—zero; or
 - (b) if the total adjusted volume of the brands of the pharmaceutical item (see step 7) is more than zero—the amount (expressed as a percentage to 2 decimal places) worked out by:
 - (i) for each brand of the pharmaceutical item, multiplying the adjusted volume of the brand for the brand's data collection period (see step 2) by the price percentage difference of the brand for the data collection period (see step 5); and
 - (ii) adding up each of those amounts; and
 - (iii) dividing that amount by the total adjusted volume of the brands of the pharmaceutical item.

37Q Step 9—Repeat steps for each pharmaceutical item with related brands

- (1) For each brand (including delisted brands) of a pharmaceutical item with the same drug and manner of administration as the listed brand but a different form (the *other pharmaceutical item*), other than an exempt item, work out the price percentage difference of the brand for the data collection period ending on the same day as the data collection period of the listed brand.
- (2) The price percentage of difference of a brand of the other pharmaceutical item is worked out using steps 1 to 5, reading references to the listed brand as references to the brand of the other pharmaceutical item.
- (3) If a brand of the other pharmaceutical item is a delisted brand on the final day, then the pricing quantity of the delisted brand on the final day is taken to be:
 - (a) if there is a listed brand of the other pharmaceutical item on the final day—the pricing quantity of the listed brand of the other pharmaceutical item; or
 - (b) if there is no listed brand of the other pharmaceutical item on the final day—the pricing quantity of the last listed brand of the other pharmaceutical item immediately before it was delisted.

Note: The pricing quantity of the brand on the final day is needed for working out the adjusted volume (step 2) and the average approved ex-manufacture price (step 3).

- (4) For each pharmaceutical item with the same drug and manner of administration as the listed brand but a different form, other than an exempt item, work out the weighted average percentage difference of the brands of the pharmaceutical item (using steps 7 and 8).

37R Step 10—Weighted average percentage difference for listed brand and all related brands

- (1) Work out the weighted average percentage difference for the listed brand and all related brands.

- (2) The ***weighted average percentage difference*** is the amount (expressed as a percentage to 2 decimal places) worked out as follows:
- (a) for each pharmaceutical item with the same drug and manner of administration as the listed brand (including the pharmaceutical item of the listed brand):
 - (i) multiply the total adjusted volume for the brands of the pharmaceutical item (see step 7) by the average approved ex-manufacturer price for a brand of the pharmaceutical item (see step 3); and
 - (ii) multiply that amount by the weighted average percentage difference of the brands of the pharmaceutical item (see step 8);
 - (b) add up the amounts worked out under subparagraph (a)(ii);
 - (c) add up the amounts worked out under subparagraph (a)(i);
 - (d) divide the amount worked out under paragraph (b) by the amount worked out under paragraph (c).
- (3) However:
- (a) if the amount worked out under paragraph (2)(c) is zero or less, the ***weighted average percentage difference*** is zero; and
 - (b) if the amount worked out under paragraph (2)(d) is 99% or more, the ***weighted average percentage difference*** is 99%.

37S Step 11—Weighted average disclosed price for listed brand of pharmaceutical item

- (1) Work out the weighted average disclosed price of the listed brand of the pharmaceutical item for the data collection period.
- (2) The ***weighted average disclosed price*** of the listed brand of the pharmaceutical item is the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).
- (3) However, if the pricing quantity of the listed brand of the pharmaceutical item on the final day is different from the pricing quantity of the listed brand on the relevant day, the ***weighted average disclosed price*** is:

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

where:

PQ1 means the pricing quantity of the listed brand on the final day.

PQ2 means the pricing quantity of the listed brand on the relevant day.

WR means the average approved ex-manufacturer price for the listed brand reduced by the weighted average percentage difference for all related brands (see step 10).

Note: See section 99ADHA of the Act for price reductions for brands listed after the end of the data collection period.

Subdivision 3—Price disclosure requirements

37T Price disclosure requirements

- (1) This regulation is made for subsection 99ADC(1) of the Act.

Prescribed information

- (2) The responsible person must provide the following information in relation to the supply of a brand of a pharmaceutical item, other than the supply to a public hospital:
- (a) the start and end dates of the period to which the information relates;
 - (b) the name of the brand;
 - (c) the name of the responsible person;
 - (d) the name of the drug in the pharmaceutical item;
 - (e) the form of the drug, including its strength;
 - (f) the manner of administration of the form of the drug;
 - (g) the number or quantity of units in a pack (the number of tablets in a pack, for example);
 - (h) the number of packs sold;
 - (i) the revenue from sales of the brand, excluding GST;
 - (j) if any incentive is given in relation to the brand:
 - (i) the kind of incentive; and
 - (ii) the value of the incentive, excluding GST.

- (3) If information is provided under paragraph (2)(i), the information must not also be provided under paragraph (2)(j).
- (4) The information mentioned in each of paragraphs (2)(h), (i) and (j), to the extent that the information relates to the brand's initial month, must be provided separately.
- (5) An amount provided under paragraph (2)(i) or (j) must be:
 - (a) expressed in Australian dollars; and
 - (b) rounded to the nearest whole dollar, rounding 50 cents upwards.

Prescribed person

- (6) The responsible person must provide the information to:
 - (a) Australian Healthcare Associates Pty Ltd (ABN 82 072 790 848); or
 - (b) if the responsible person receives written notice from the Department to provide the information to the Secretary—the Secretary.

Prescribed manner and form

- (7) The responsible person must provide the information in a form approved by the Secretary.
- (8) The completed form must:
 - (a) include all the statements and information required by the form; and
 - (b) be signed (or authorised for electronic transmission) by a person who is authorised by the responsible person to provide the information.

Prescribed times

- (9) Subject to subregulation (10), the responsible person must provide the information:
 - (a) for each period between 1 April and 30 September in a year—before the end of 11 November in that year; and
 - (b) for each period between 1 October and the next 31 March—before the end of the next 12 May.

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- (10) However, for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person must provide the information:
- (a) if the start day happens between 1 April and 30 September in a year—before the end of 11 November in that year; or
 - (b) if the start day happens between 1 October and the next 31 March—before the end of the next 12 May.

6 Division 1 of Part 8

Repeal the Division.

7 Regulations 51 and 52

Repeal the regulations.

8 At the end of Part 8

Add:

Division 3—Provisions for National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014

54 Application of Regulations

- (1) These Regulations, as amended by the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*, apply in relation to a data collection period that ends after 1 February 2014.
- (2) This regulation applies subject to regulation 55.

55 Data collection periods

- (1) The data collection period for a brand that, under the old Regulations:
 - (a) started on a date, or between the dates, mentioned in column 1 of the following table (the *brand's start date*); and
 - (b) was due to end on the date mentioned in column 2 of the table;instead ends on the date mentioned in column 3 of the table.

Schedule 1 Amendments

New data collection period end dates			
Item	Column 1	Column 2	Column 3
	Starts on or between	Due to end on	Instead ends on
1	1 February 2013	30 September 2014	31 March 2014
2	2 February 2013 to 1 June 2013	31 May 2014	31 March 2014
3	1 June 2013	30 September 2014	31 March 2014
4	2 June 2013 to 1 October 2013	30 September 2014	31 March 2014
5	1 October 2013	30 September 2014	31 March 2014
6	2 October 2013 to 1 February 2014	31 January 2015	30 September 2014
7	1 February 2014	30 September 2015	30 September 2014
8	2 February 2014 to 1 April 2014	31 May 2015	30 September 2014
9	2 April 2014 to 1 June 2014	31 May 2015	31 March 2015

- (2) If the brand is a listed brand, the next data collection period for the brand starts on the day after the date mentioned in column 3 of the table.
- (3) The responsible person for a brand to which item 6, 7 or 8 of the table applies must provide the information required under regulation 37H of the old Regulations for the period between the brand's start date and 31 March 2014, in accordance with regulations 37HA to 37J of the old Regulations, before the end of 12 May 2014.
- (4) In this regulation:

brand means a listed or delisted brand of a pharmaceutical item, other than an exempt item.

old Regulations means these Regulations as in force immediately before these Regulations were amended by the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*.

56 Expiry of this Division

This Division expires on 3 April 2016 as if it had been repealed by another regulation.

9 Schedules 7 and 8

Repeal the Schedules.

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