



National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)¹

Select Legislative Instrument 2012 No. 168

I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the *National Health Act 1953* and the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*.

Dated 12 July 2012

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

TANYA PLIBERSEK
Minister for Health

1 Name of regulation

This regulation is the *National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)*.

2 Commencement

This regulation commences on 1 October 2012.

3 Amendment of *National Health (Pharmaceutical Benefits) Regulations 1960*

Schedule 1 amends the *National Health (Pharmaceutical Benefits) Regulations 1960*.

Schedule 1 Amendments

(section 3)

[1] Subregulation 5 (1), definition of *authority prescription*

omit

subsection 85B (5)

insert

subsection 85B (4)

[2] Regulation 15

substitute

15 Prescriber bag supplies—practitioners on ships

A practitioner who is practising his or her profession on a ship is not authorised to supply pharmaceutical benefits under section 93, 93AA or 93AB of the Act.

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- [3] Regulation 16, heading**
substitute
- 16 Prescriber bag supplies—obtaining benefits by practitioners**
- [4] Subregulation 16 (1)**
omit
and 93AA
insert
, 93AA and 93AB
- [5] Regulation 17, heading**
substitute
- 17 Prescriber bag supplies—supply of pharmaceutical benefits by approved pharmacists**
- [6] Regulation 18, heading**
substitute
- 18 Prescriber bag supplies—payment for pharmaceutical benefits**
- [7] Regulation 18**
omit
or 93AA
insert
, 93AA or 93AB

[8] Subregulation 19 (6)

omit

subsection 85B (5)

insert

subsection 85B (4)

[9] Paragraph 36 (2) (c)

omit

or 93AA (2)

insert

, 93AA (2) or 93AB (2)

[10] Subregulation 36 (3), note

omit

subsection 85B (2)

insert

subsection 85B (5)

[11] Regulation 37A, definition of *approved price to pharmacists*

omit

[12] Regulation 37A

insert

start day, in relation to a brand of a pharmaceutical item, means the day on which the price disclosure requirements first apply under section 99ADD of the Act for the brand.

[13] Regulation 37C

omit

[14] Regulation 37D

omit

[15] Regulation 37DA

omit

[16] Subregulation 37ED (1)

substitute

- (1) This regulation applies to a listed brand of a pharmaceutical item (the ***relevant brand***) if no requirement to comply with the price disclosure requirements has arisen under the Act before the start day for the relevant brand for:
 - (a) the relevant brand; or
 - (b) any other listed brand of any pharmaceutical item having the same drug and manner of administration as the relevant brand.

[17] Subregulation 37ED (6), note

omit

[18] Before subregulation 37EE (1)

insert

- (1A) This regulation applies to a relevant brand mentioned in subregulation 37ED (1).

[19] Subregulation 37EE (5)

omit

[20] Regulation 37F

substitute

37F Listed brand having same drug and manner of administration as listed brand already subject to price disclosure requirements—first disclosure cycle and beginning of data collection period for brand

- (1) This regulation applies to a listed brand of a pharmaceutical item (the *relevant brand*) if the price disclosure requirements apply to any other listed brand of any pharmaceutical item (the *other brand*) having the same drug and manner of administration as the relevant brand both:
 - (a) before the start day for the relevant brand; and
 - (b) on the start day for the relevant brand.
- (2) If the end of a data collection period for a disclosure cycle (the *relevant disclosure cycle*) for the other brand is after the start day for the relevant brand, then:
 - (a) the relevant brand is in the relevant disclosure cycle; and
 - (b) the relevant brand joins the data collection period for the other brand on the start day for the relevant brand.
- (3) If:
 - (a) the other brand is in both:
 - (i) the relevant disclosure cycle; and
 - (ii) a disclosure cycle (the *prior disclosure cycle*) before the relevant disclosure cycle; and
 - (b) the start day for the relevant brand is before the reduction day for the other brand in the prior disclosure cycle;
then the relevant brand is also in the prior disclosure cycle.
- (4) If:
 - (a) subregulation (3) applies to a relevant brand; and
 - (b) no other brand of that pharmaceutical item was subject to the price disclosure requirements on both:
 - (i) the day before the start day for the relevant brand; and

- (ii) the start day for the relevant brand;

then the relevant brand is in the data collection period for the other brand, for the purposes of calculating the weighted average disclosed price for the relevant brand.

Note Although data is not required to be provided for the relevant brand for the prior disclosure cycle, a weighted average disclosed price is determined for the relevant brand using the method in regulation 37G. Regulation 37FA provides a method for working out the approved ex-manufacturer price on the last day of the data collection period in the prior disclosure cycle.

37FA Approved ex-manufacturer price on relevant day

- (1) This regulation prescribes the method for working out the approved ex-manufacturer price of a brand of a pharmaceutical item (a **relevant brand**) on the relevant day for the prior disclosure cycle if:
- (a) regulation 37F applies to the relevant brand; and
 - (b) the circumstances mentioned in subregulation 37F (4) apply to the relevant brand.

Note 1 Regulation 37F applies to listed brands of pharmaceutical items that have the same drug and manner of administration as listed brands that are already subject to price disclosure requirements.

Note 2 For the definition of **relevant day**, see subsection 99ADB (1) of the Act.

- (2) This regulation does not apply to a relevant brand if:
- (a) the relevant day is 1 October 2012; and
 - (b) the start day for the relevant brand is also 1 October 2012.
- (3) The method for working out the approved ex-manufacturer price of a relevant brand on the relevant day for the prior disclosure cycle is to add the following amounts together:
- (a) the approved ex-manufacturer price of the relevant brand on the start day for the relevant brand; and

- (b) any amount that would have been deducted from the approved ex-manufacturer price, under the price reduction provisions, if the relevant brand had been a listed brand in the period that:
 - (i) begins on the relevant day for the prior disclosure cycle; and
 - (ii) ends on the start day for the relevant brand.

(4) In this regulation:

price reduction provisions means Division 3A of Part VII of the Act.

prior disclosure cycle has the meaning given by subregulation 37F (3).

(5) This regulation is made for paragraph 99ADB (3B) (c) of the Act.

[21] Paragraphs 37G (3) (a) and (6) (a)

omit

relevant day mentioned in paragraph 37ED (1) (a)

insert

start day for the brand

[22] Subregulation 37G (14)

omit

every brand of every

insert

each brand of each

[23] Subregulation 37G (14)

omit

brands

insert

brand

[24] Subregulation 37G (15)

substitute

(15) In this regulation:

adjusted volume, of a listed brand of a pharmaceutical item that is sold, means the volume worked out as if the pack sizes in which the brand was sold were equivalent to the pricing quantity of the brand on the relevant day.

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

[25] Paragraphs 37H (1) (i) and (j)

omit

given for

insert

given in relation to

[26] Paragraph 37J (3) (a)

omit

relevant day mentioned in regulation 37ED

insert

start day

[27] Paragraph 37J (3) (b)

omit

relevant

insert

start

[28] Paragraph 37J (4) (a)

omit

relevant day mentioned in regulation 37F

insert

start day for the relevant brand

[29] Subparagraph 37J (4) (b) (ii)

omit

relevant

insert

start

[30] After Part 7

insert

Part 8 Transitional provisions

Division 1 Provisions for *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*

49 Approved ex-manufacturer prices on 1 October 2012

- (1) Schedule 7 sets out the approved ex-manufacturer price on 1 October 2012 for each brand of a pharmaceutical item listed in Schedule 7.

- (2) This regulation is made for paragraph 70 (a) of Schedule 1 to the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*.

50 Determination of weighted average disclosed price

- (1) This regulation applies if:
- (a) the weighted average disclosed price of a listed brand of a pharmaceutical item is determined on or before 30 September 2012; and
 - (b) after 30 September 2012, another weighted average disclosed price (a *new price*) is to be determined for the listed brand for the same disclosure cycle.
- (2) The new price must be determined according to the provisions of these regulations as in force immediately before 1 October 2012.

[31] After Schedule 6

insert

Schedule 7 Approved ex-manufacturer prices on 1 October 2012

(regulation 49)

Brand of pharmaceutical item					
Item	Drug	Form	Manner of administration	Brand	Approved ex-manufacturer price (\$)
1	Doxorubicin-Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Caelyx	622.99
2	Doxorubicin-Pegylated Liposomal	Suspension for I.V. infusion containing pegylated liposomal doxorubicin hydrochloride 20 mg in 10 mL	Injection	Lipodox	622.99
3	Etanercept	Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL	Injection	Enbrel	815.00
4	Follitropin Alfa	Injection 300 I.U. in 0.5 mL multi-dose cartridge	Injection	Gonal-f Pen	144.00

Brand of pharmaceutical item					
Item	Drug	Form	Manner of administration	Brand	Approved ex-manufacturer price (\$)
5	Follitropin Alfa	Injection 450 I.U. in 0.75 mL multi-dose cartridge	Injection	Gonal-f Pen	216.00
6	Follitropin Alfa	Injection 900 I.U. in 1.5 mL multi- dose cartridge	Injection	Gonal-f Pen	432.00
7	Follitropin Beta	Solution for injection 300 I.U. in 0.36 mL multi-dose cartridge	Injection	Puregon 300 IU/0.36 mL	144.04
8	Follitropin Beta	Solution for injection 450 I.U. in 0.72 mL multi-dose cartridge	Injection	Puregon 600 IU/0.72 mL	288.09
9	Follitropin Beta	Solution for injection 900 I.U. in 1.08 mL multi-dose cartridge	Injection	Puregon 900 IU/1.08 mL	432.11
10	Rituximab	Solution for I.V. infusion 500 mg in 50 mL	Injection	Mabthera	2 263.57
11	Temozolomide	Capsule 100 mg	Oral	Astromide	602.32

Brand of pharmaceutical item

Item	Drug	Form	Manner of administration	Brand	Approved ex-manufacturer price (\$)
12	Temozolomide	Capsule 100 mg	Oral	Temizole 100	602.32
13	Temozolomide	Capsule 100 mg	Oral	Temodal	602.32
14	Temozolomide	Capsule 140 mg	Oral	Astromide	830.65
15	Temozolomide	Capsule 140 mg	Oral	Temizole 140	830.65
16	Temozolomide	Capsule 140 mg	Oral	Temodal	830.65

[32] Further amendments—start day

The following provisions are amended by omitting each mention of ‘relevant day’ and inserting ‘start day’:

- regulation 37ED
- regulation 37EE.

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003*. See www.comlaw.gov.au.