National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)

Select Legislative Instrument No. 53, 2013

I, Professor Marie Bashir AC CVO, Administrator of the Government of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulation under the *National Health Act 1953*.

Dated 11 April 2013

Marie Bashir
Administrator

By Her Excellency's Command

Tanya Plibersek
Minister for Health

OPC50322 - C

Contents

OPC50322 - C

1 Name of regulation

This regulation is the *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)*.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceutical Benefits) Regulations 1960

1 Part 6A (heading)

Repeal the heading, substitute:

Part 6A—Price reductions and price disclosures

2 Regulation 37A

Insert:

delisted brand means a brand that:

(a) was a listed brand during a data collection period in a disclosure cycle; and

(b) during the disclosure cycle, the Minister revokes or varies the determination made under subsection 85(6) of the Act in relation to the brand so that, on the reduction day for a listed brand that has the same drug and manner of administration as the brand, there is no longer a determination in force in relation to the brand.

3 Regulation 37A (definition of *listed*)

Repeal the definition.

4 Regulation 37A

Insert:

listed brand has the same meaning as in subsection 84(1) of the Act.

relevant day has the same meaning as in subsection 99ADB(1) of the Act.

5 Regulation 37A (definition of *reporting period*)

Omit "for a brand of a pharmaceutical item".

6 Regulation 37A (definition of *start day*)

Repeal the definition, substitute:

start day means:

(a) in relation to a listed brand, the day on which the price disclosure requirements first apply under section 99ADD of the Act for the listed brand; and

(b) in relation to a delisted brand, the day on which the price disclosure requirements first applied under section 99ADD of the Act to the brand before it became a delisted brand.

7 After regulation 37A

Insert:

Division 1A—Price reductions

8 Subregulations 37E(2), (3) and (4)

Repeal the subregulations, substitute:

(2) To use the method to determine the weighted average disclosed price of a listed brand (a ***particular brand***), all the information required under the price disclosure requirements must have been provided for the whole of the data collection period for:

(a) the particular brand; or

(b) another listed brand of a pharmaceutical item that has the same drug and manner of administration as the particular brand; or

(c) a combination of listed or delisted brands of a pharmaceutical item if:

(i) each brand has the same drug and manner of administration as the particular brand; and

(ii) the information provided for each brand, when combined, results in information being provided under the price disclosure requirements for the whole of the data collection period.

(3) Information provided by a responsible person under the price disclosure requirements may be disregarded in making a determination of the weighted average disclosed price of the

particular brand or every listed brand of every pharmaceutical item with the same drug and manner of administration if:

(a) for a listed brand—the information provided for a reporting period is incomplete; or

(b) for a delisted brand—the information provided for a reporting period while the brand was a listed brand is incomplete.

Note: For the meaning of ***reporting periods***, see regulations 37J and 37JA.

9 Paragraph 37EB(1)(c)

Repeal the paragraph, substitute:

(c) one or more reduction days occur.

10 Subregulation 37EB(2) (notes 1 and 2)

Repeal the notes, substitute:

Note 1: See regulations 37ED and 37F to work out the first disclosure cycle for a listed brand of pharmaceutical item.

Note 2: Regulations 37EG and 37EH set out when a listed brand of a pharmaceutical item moves from a supplementary disclosure cycle to a main disclosure cycle.

11 Subregulation 37EC(1)

Repeal the subregulation, substitute:

(1) In each disclosure cycle, there are ***data collection periods*** for which information must be provided in compliance with price disclosure requirements for:

(a) listed brands; and

(b) delisted brands but only in relation to the period that the delisted brand was a listed brand.

12 Paragraph 37EC(2)(a)

Omit "brand of a pharmaceutical item", substitute "listed and delisted brand".

13 Paragraphs 37EC(2)(b) and (c)

Omit "brands of pharmaceutical items", substitute "listed and delisted brands".

14 Regulation 37EF

Omit "brand" (wherever occurring), substitute "listed brand".

15 Paragraph 37EG(1)(a) and subregulations 37EG(2) and (3)

Omit "brand", substitute "listed brand".

16 Paragraph 37EH(1)(a) and subregulations 37EH(2) and (3)

Omit "brand", substitute "listed brand".

17 Regulation 37F (heading)

Repeal the heading, substitute:

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

18 Subregulation 37F(1)

Repeal the subregulation, substitute:

(1) This regulation applies to a listed brand of a pharmaceutical item (the ***relevant brand***) if:

(a) the price disclosure requirements apply to any other listed brand of any pharmaceutical item having the same drug and manner of administration as the relevant brand both:

(i) before the start day for the relevant brand; and

(ii) on the start day for the relevant brand; or

(b) if there is no other listed brand of the kind mentioned in paragraph (a)—both:

(i) the price disclosure requirements applied to a delisted brand having the same drug and manner of administration as the relevant brand; and

(ii) the end of the data collection period for the delisted brand is after the start day for the relevant brand.

19 Paragraph 37F(3)(b)

Omit "day for the other brand in the prior disclosure cycle", substitute "day, in the prior disclosure cycle, for a listed brand having the same drug and manner of administration as the relevant brand".

20 Paragraph 37F(4)(b)

Omit "no other", substitute "no other listed".

21 At the end of regulation 37F

Add:

(5) In this regulation:

other brand means:

(a) the listed brand mentioned in paragraph (1)(a); or

(b) the delisted brand mentioned in paragraph (1)(b).

22 Subregulation 37FA(1)

Omit "brand of", substitute "listed brand of".

23 Subregulation 37FA(1) (notes 1 and 2)

Repeal the notes.

24 Subregulation 37FA(3)

Repeal the subregulation, substitute:

(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 as follows:

(a) add the following amounts together:

(i) the approved ex-manufacturer price of the relevant brand on the start day for the relevant brand; and

(ii) any amount that would have been deducted from the approved ex-manufacturer price, as the result of a price adjustment, if the relevant brand had been a listed brand in the period that:

(A) began on the relevant day for the prior disclosure cycle; and

(B) ended on the start day for the relevant brand; and

(b) deduct from the amount worked out in paragraph (a), any amount that would have been added to the approved ex-manufacturer price, under a price agreement or price determination, if the relevant brand had been a listed brand in the period that:

(i) began on the relevant day for the prior disclosure cycle; and

(ii) ended on the start day for the relevant brand.

25 Subregulation 37FA(4)

Insert:

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 agreement has the same meaning as in Part VII of the Act.

price determination has the same meaning as in Part VII of the Act.

26 Subregulation 37FA(4) (definition of *price reduction provisions*)

Repeal the definition.

27 Subregulation 37G(1)

Omit "the brands", substitute "the listed brands".

28 At the end of subregulation 37G(5)

Add:

Note: For the meaning of ***adjusted volume***, see subregulation (16).

29 Subregulation 37G(6)

Repeal the subregulation.

30 Subregulations 37G(7) and (8)

Repeal the subregulations, substitute:

Step 4

(7) Work out the disclosed price for the brand as follows:
  (a) if the brand's adjusted volume is greater than zero, divide the net revenue for the brand by its adjusted volume; and
  (b) if the adjusted volume is zero or less, the disclosed price is zero.

Step 5

(8) Work out the price percentage difference for the brand (expressed as a percentage to 2 decimal places) by:
  (a) if the brand is a listed brand on the relevant day:
    (i) subtracting the brand's disclosed price from the brand's applicable approved ex-manufacturer price; and
    (ii) dividing that amount by the brand's applicable approved ex-manufacturer price; or
  (b) if the brand is a delisted brand on the relevant day and on that day there is a listed brand of the same pharmaceutical item as the delisted brand:
    (i) subtracting the brand's disclosed price from the listed brand's applicable approved ex-manufacturer price; and
    (ii) dividing that amount by the listed brand's applicable approved ex-manufacturer price; or
  (c) if the brand is a delisted brand on the relevant day and on that day there is no listed brand of the same pharmaceutical item as the delisted brand:
    (i) subtracting the brand's disclosed price from the pharmaceutical item price; and
    (ii) dividing that amount by the pharmaceutical item price.

Note: For the meaning of ***pharmaceutical item price***, see subregulation (16).

31 After subregulation 37G(11)

Insert:

(11A) However, if the amount worked out in paragraph (c) is zero or less, the weighted average percentage difference for the pharmaceutical item is zero.

32 Subregulations 37G(13), (14) and (15)

Repeal the subregulations, substitute:

Step 10

(13) Work out the weighted average percentage difference (expressed as a percentage to 2 decimal places) for every brand of every pharmaceutical item having the same drug and manner of administration in the following way:

(a) for each pharmaceutical item where there is at least one listed brand of the pharmaceutical item on the relevant day:

(i) multiply the total adjusted volume of the pharmaceutical item by the applicable approved ex-manufacturer price for the listed brand of the pharmaceutical item; and

(ii) multiply the percentage worked out in step 8 by the amount worked out under subparagraph (i);

(b) for each pharmaceutical item where there is no listed brand of the pharmaceutical item on the relevant day:

(i) multiply the total adjusted volume of the pharmaceutical item by the pharmaceutical item price; and

(ii) multiply the percentage worked out in step 8 by the amount worked out under subparagraph (i);

(c) add up the amounts worked out for each pharmaceutical item under subparagraphs (a)(ii) and (b)(ii);

(d) add up the amounts worked out for each pharmaceutical item under subparagraphs (a)(i) and (b)(i);

(e) divide the amount worked out under paragraph (c) by the amount worked out under paragraph (d).

Note: For the meaning of ***pharmaceutical item price***, see subregulation (16).

(14) However, if the sum of the amounts worked out under paragraph (d) is zero or less, the weighted average percentage difference for every brand of every pharmaceutical item having the same drug and manner of administration is zero.

Step 11

(15) The weighted average disclosed price for each listed brand of each pharmaceutical item that has the same drug and manner of administration is the applicable approved ex-manufacturer price for the listed brand reduced by the percentage worked out under step 10.

(16) In this regulation:

adjusted volume means:

(a) for a listed brand—the volume of the listed brand sold worked out as if pack sizes in which the listed brand was sold were equivalent to the pricing quantity of the listed brand on the relevant day and any excluded adjusted volume has been subtracted; or

(b) for a delisted brand where there is a listed brand of the same pharmaceutical item as the delisted brand on the relevant day—the volume of the delisted brand sold (when the delisted brand was a listed brand) worked out as if the pack sizes in which the brand was sold were equivalent to the pricing quantity of a listed brand of the same pharmaceutical item on the relevant day and any excluded adjusted volume has been subtracted; or

(c) for a delisted brand where there is no other listed brand of the same pharmaceutical item as the delisted brand on the relevant day—the volume of the delisted brand sold (when the delisted brand was a listed brand) worked out as if the pack sizes in which the delisted brand was sold were equivalent to the pricing quantity of the last listed brand of the same pharmaceutical item as the delisted brand immediately prior to the date that the last listed brand became a delisted brand and any excluded adjusted volume has been subtracted.

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

Note 2: For the ***pricing quantity*** of a delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012, see Division 2 of Part 8.

brand includes:

(a) a listed brand; and
(b) a delisted brand.

excluded adjusted volume, for a brand:

(a) that subregulation 37J(3) applies to for the reporting period and that was not a listed brand immediately before the start day for the brand; or
(b) that subregulation 37J(4) applies to for the reporting period for the brand;

means the volume of the brand that is sold in the first month of the first reporting period worked out as if:

(c) for a listed brand—the pack sizes in which the brand was sold were equivalent to the pricing quantity of the listed brand on the relevant day; or
(d) for a delisted brand where there is a listed brand of the same pharmaceutical item as the delisted brand on the relevant day—the pack sizes in which the delisted brand was sold were equivalent to the pricing quantity of a listed brand of the same pharmaceutical item on the relevant day; or
(e) for a delisted brand where there is no other listed brand of the same pharmaceutical item as the delisted brand on the relevant day—the pack sizes in which the delisted brand was sold were equivalent to the pricing quantity of the last listed brand of the same pharmaceutical item as the delisted brand immediately prior to the date that the last listed brand became a delisted brand.

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

Note 2: For the ***pricing quantity*** of a delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012, see Division 2 of Part 8.

last approved ex-manufacturer price, for a delisted brand, means the approved ex-manufacturer price of the last listed brand of the same pharmaceutical item as the delisted brand immediately before the last listed brand became a delisted brand.

pharmaceutical item price, for a delisted brand, means the amount worked out in the following way:

(a) deduct from the last approved ex-manufacturer price for the delisted brand any amount that would have been deducted as the result of a price adjustment if the delisted brand had been a listed brand in the period that:
  (i) began on the day that the brand was delisted; and
  (ii) ended on the relevant day;

(b) add to the amount worked out in paragraph (a) any amount that would have been added to the last approved ex-manufacturer price for the delisted brand, under a price agreement or price determination, if the delisted brand had been a listed brand in the period that:
  (i) began on the day that the brand was delisted; and
  (ii) ended on the relevant day.

Note: To work out the ***pharmaceutical item price*** of a delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012, see Division 2 of Part 8.

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 agreement has the same meaning as in Part VII of the Act.

price determination has the same meaning as in Part VII of the Act.

total adjusted volume, in relation to a pharmaceutical item, means the sum of the adjusted volume for each of the brands of the pharmaceutical item.

33 Subregulation 37H(1) (note 1)

Omit "*Note 1*", substitute "*Note*".

34 Subregulation 37H(1) (note 2)

Repeal the note.

35 After subregulation 37H(1)

Insert:

(1A) For a delisted brand, the information mentioned in subregulation (1) is to be provided for the supply of a delisted brand for a reporting period but only in relation to supplies made while the delisted brand was a listed brand.

36 Subregulation 37H(2)

Omit "37G(3) or (6)", substitute "37J(3) or (4)".

37 Subregulation 37H(3)

Omit "brand" (first occurring), substitute "listed brand, including a delisted brand while it was a listed brand".

38 Subregulation 37H(6)

Omit "brand" (first occurring), substitute "listed brand, including a delisted brand while it was a listed brand".

39 At the end of subregulation 37HA(2)

Add:

Note: For a delisted brand, the responsible person remains responsible for providing information in relation to supplies made while the delisted brand was a listed brand: see subregulation 37H(1A).

40 At the end of subregulation 37I(2)

Add:

Note: For a delisted brand, the responsible person remains responsible for providing information in relation to supplies made while the delisted brand was a listed brand: see subregulation 37H(1A).

41 Subregulation 37J(1)

Repeal the subregulation, substitute:

(1) For paragraph 99ADC(1)(c) of the Act, the information mentioned in regulation 37H must be provided within 6 weeks after:

(a) for a listed brand—the end of each reporting period for the listed brand; or

(b) for a delisted brand—the end of the reporting period in which the brand was delisted.

42 Subregulations 37J(2), (5) and (6)

Omit "brand" (wherever occurring), substitute "listed brand".

43 Subregulation 37J(6) (note)

Repeal the note.

44 At the end of regulation 37J

Add:

(7) Subregulations (2) to (6) also apply to a delisted brand but only until the end of the reporting period in which the brand was delisted.

45 Subregulation 37JA(6) (note)

Repeal the note.

46 At the end of regulation 37JA

Add:

(7) This regulation also applies to a delisted brand but only until the end of the reporting period in which the brand was delisted.

47 At the end of Part 8

Add:

Division 2 Amendments made by National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)

51 Application of regulation 37G for delisted brands where all brands of the same pharmaceutical item are delisted before 1 October 2012

For the purpose of working out the weighted average disclosed price under regulation 37G, this Division sets out the pharmaceutical item price and pricing quantity for a delisted brand that does not have a last approved ex-manufacturer price or a pricing quantity because:

(a) the delisted brand was delisted before 1 October 2012; and

(b) all brands of the same pharmaceutical item as the delisted brand were delisted before 1 October 2012.

Note 1: Pricing quantity is used for working out adjusted volume and excluded adjusted volume, see subregulation 37G(16).

Note 2: For the meaning of ***last approved ex-manufacturer price*** see subregulation 37G(16).

52 Pharmaceutical item price and pricing quantity for delisted brands in main disclosure cycle with relevant day of 1 October 2012

(1) The pharmaceutical item price for a delisted brand mentioned in an item of the table in Schedule 8 is the amount specified for the delisted brand in column 5.

(2) The pricing quantity for a delisted brand mentioned in an item of the table in Schedule 8 is the amount specified for the delisted brand in column 6.

53 Pharmaceutical item price and pricing quantity for delisted brands in main disclosure cycle with relevant day of 30 September 2013

(1) The pharmaceutical item price for a delisted brand mentioned in an item of the table in Schedule 9 is to be worked out in the following way:

(a) deduct from the amount specified for the delisted brand in column 5 any amount that would have been deducted as the result of a price adjustment if the delisted brand was a listed brand in the period that:

(i) began on the commencement of the *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)*; and

(ii) ended on the relevant day;

(b) add to the amount worked out in paragraph (a) any amount that would have been added to the amount specified in column 5 under a price agreement or price determination if the delisted brand had been a listed brand in the period that:

(i) began on the commencement of the *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)*; and

(ii) ended on the relevant day.

(2) The pricing quantity for a delisted brand mentioned in an item of the table in Schedule 9 is the amount specified for the delisted brand in column 6.

(3) In this regulation:

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 agreement has the same meaning as in Part VII of the Act.

price determination has the same meaning as in Part VII of the Act.

relevant day has the same meaning as in subsection 99ADB(1) of the Act.

48 At the end of the regulations

Add:

Schedule 8—Pharmaceutical item price and pricing quantity for certain delisted brands with main disclosure cycle relevant day of 1 October 2012

Note: See regulation 52.

Pharmaceutical item price and pricing quantity for certain delisted brands

Item	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Drug	**Form**	**Manner of administration**	**Brand**	**Pharmaceutical item price**	**Pricing quantity**
1	Amoxycillin	Sachet containing oral powder 3 g (as trihydrate)	Oral	Amoxil	$1.33	1
2	Cisplatin	I.V. injection 10 mg in 10 mL	Injection	Pfizer Australia Pty Ltd	$2.78	1
3	Oestradiol	Transdermal patches 2 mg, 8	Transdermal	Estraderm 25	$8.63	1
4	Oestradiol	Transdermal patches 8 mg, 8	Transdermal	Estraderm 100	$10.28	1
5	Verapamil	Tablet containing verapamil hydrochloride 160 mg	Oral	Isoptin	$9.24	60

Schedule 9—Pharmaceutical item price and pricing quantity for certain delisted brands with main disclosure cycle relevant day of 30 September 2013

Note: See regulation 53.

Pharmaceutical item price and pricing quantity for certain delisted brands

Item	Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
	Drug	**Form**	**Manner of administration**	**Brand**	**Pharmaceutical item price**	**Pricing quantity**
1	Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent	Injection	Taxotere	$68.61	1
2	Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 20 mg in 10 mL single dose vial	Injection/ intravesical	Adriamycin Solution	$8.24	1
3	Mitozantrone	Injection 10 mg (as hydrochloride) in 5 mL	Injection	Pfizer Australia Pty Ltd	$53.34	1