EXPLANATORY STATEMENT

Select Legislative Instrument 2013 No. 53

National Health Act 1953

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

Section 140 of the *National Health Act 1953* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which are required or permitted to be prescribed, or which are necessary or convenient to be prescribed, for carrying out or giving effect to the Act.

The regulation amends Part 6A of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations), which makes provision in relation to price disclosure arrangements under the Pharmaceutical Benefits Scheme (PBS).

The Pharmaceutical Benefits Scheme (PBS) operates under Part VII of the Act which provides for and regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits. Under price disclosure arrangements in Division 3B of Part VII of the Act pharmaceutical companies responsible for the supply of certain pharmaceutical benefits (responsible persons) are required to disclose specified information about sales of those medicines to the Department of Health and Ageing.

Part 6A of the Principal Regulations makes provision for collection of the sales information required to be disclosed under the Act, and a method (the price disclosure method) for using that information in calculations that are the basis for potential reductions in the PBS subsidised price for the medicines.

The regulation makes changes to the provisions in Part 6A of the Principal Regulations reflecting the reasons in the December 2012 *Sanofi-Aventis Australia Pty Limited v Minister for Health* Federal Court judgment (the judgment). The judgment concerned interpretation of price disclosure provisions in the Act and Principal Regulations for certain brands delisted from the PBS. Brands may be removed or delisted from the PBS for various reasons, generally associated with a commercial decision of the company supplying the brand. The practice was not to collect or use information for delisted brands in the price disclosure method. The regulation reflects the judgment, which provided that delisted brand information is to be collected and used in the price disclosure method.

The regulation amends the Principal Regulations to:

- provide that a price disclosure cycle can have more than one reduction day. Previously, information was disclosed and calculations were done for a cycle covering specific medicines over a specific period, with a day for potential price reductions at the end of the cycle. There are situations when there may need to be more than one day for potential price reductions at the end of a cycle, with different reduction days for different medicines. This is the case for medicines impacted by the change in approach to delisted brands following the judgment. The regulation provides for this situation;

- make provision for collection of delisted brand data, and use of that data in the price disclosure method for a listed brand, including where there are no longer any brands of the relevant pharmaceutical item on the PBS;
- make related amendments concerning the data to be used in the price disclosure method. These include the use of information about the volume of sales of medicines disclosed by responsible persons throughout the price disclosure method. Previously, the method used two different sources of volume information for medicines, which is no longer considered necessary once delisted brand information is included in the price disclosure method. In addition, there was previously a requirement for a set of continuous data to be disclosed by a single brand for the whole data collection period before the price disclosure method was used. The regulation provides that the requirement for continuous data may be fulfilled using data provided by more than one listed or delisted brand with the same drug and manner of administration; and
- provide a technical clarification that the result of a calculation under the price disclosure method that has zero or less than zero as the denominator will be zero.

Details of the regulation are set out in the Attachment.

The Act specifies no conditions that need to be met before the power to make the regulation may be exercised.

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on the day after it is registered.

All pharmaceutical companies with PBS listed medicines and representatives of the medicines industry, consumer, pharmacy and wholesaler organisations were briefed in December 2012 regarding the outcome of the judgment, and its potential impact for price disclosure arrangements. Further briefings were provided in March 2013 concerning the proposals to amend the Principal Regulations reflecting the judgment. Companies affected by the transitional provisions were specifically consulted about the price for their brand of pharmaceutical item included in the regulation. No significant issues were raised.

Authority: Section 140 of the *National Health Act 1953*

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)*

Section 1 – Name of regulation

This section provides that the title of the regulation is the *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1).*

Section 2 – Commencement

This section provides for the regulation to commence on the day after it is registered.

Section 3 – Authority

This section provides that the regulation is made under the *National Health Act 1953* (the Act).

Section 4 – Schedules

This section provides that 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

Item [1] – Part 6A

This item substitutes a more descriptive heading for Part 6A.

Item [2] – Regulation 37A

This item inserts a definition of a new term, ***delisted brand***, in regulation 37A.

A ***delisted brand*** is one that was a ***listed brand*** during a data collection period in a disclosure cycle and, during the disclosure cycle the Minister revokes or varies the brand determination in relation to that brand so that, on the reduction day for a ***listed brand*** with the same drug and manner of administration, the brand is no longer a ***listed brand***.

The term has been inserted so that specific provision can be made concerning ***delisted brands*** subject to price disclosure, including for application of the method under Regulation 37G for working out a weighted average disclosed price (the price disclosure method).

Item [3] – Regulation 37A, definition of listed

This item repeals the definition of ***listed***, which is used in Part 6A of the Principal Regulations. The definition is no longer needed because this regulation also provides that the term ***listed brand*** has the same meaning as in the Act.

The inclusion of a definition for ***delisted brand***, and the alignment of definitions for the term ***listed brand*** in the Principal Regulations and the Act ensures that specific provision can be made for ***delisted brands*** without impacting all provisions in the Principal Regulations that

do not concern ***delisted brands***.

Item [4] – Regulation 37A

This item inserts definitions for the terms ***listed brand*** and ***relevant day*** in regulation 37A. In conjunction with the repeal of the definition for the term ***listed***, the insertion of a definition for ***listed brand*** ensures alignment of definitions for the term ***listed brand*** in the Principal Regulations and the Act. Under the Act, a ***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.

The inclusion of a definition for ***relevant day*** also ensures alignment between the Principal Regulations and the Act. Under the Act, ***relevant day*** means:

(a) if 30 September 2012 is the last day of the period in respect of which the weighted average disclosed price of a brand of the pharmaceutical item is determined—1 October 2012; and
(b) otherwise – the last day of the period in respect of which the weighted average disclosed price of the brand of the pharmaceutical item is determined.

Item [5] – Regulation 37A, definition of reporting period

This item removes the words "for a brand of a pharmaceutical item" from the definition of reporting period. Reference to reporting periods being "for a brand of a pharmaceutical item" would inappropriately confine the definition because this instrument also amends regulations 37J and 37JA to specifically provide for reporting periods in relation to both ***listed brands*** and ***delisted brands***.

Item [6] - Regulation 37A, definition of start day

This item substitutes a new definition of ***start day*** to provide a consistent meaning for ***start day*** for both a ***listed brand*** and a ***delisted brand***.

The ***start day*** is, for a ***listed brand***, the day on which price disclosure requirements first apply under section 99ADD of the Act for the ***listed brand***. For a ***delisted brand***, the ***start day*** is the day on which the price disclosure requirements first applied under section 99ADD of the Act for that brand before it was delisted.

The day referred to in these definitions is the same day referred to in previous regulation 37A as the start day in relation to a brand of pharmaceutical item.

Item [7] – After Regulation 37A

This item inserts a new heading for new Part 6A Division 1A of the Principal Regulations. The new Division consists of regulation 37B, which is unchanged.

Item [8] – Subregulations 37E(2), (3) and (4)

This item substitutes new subregulations 37E(2) and (3) for previous subregulations 37E(2), (3) and (4).

These subregulations refer to the set of data required to be disclosed before the price disclosure method may be completed for a listed brand.

The new subregulation 37E(2) provides that, before the price disclosure method can be used for a listed brand (a particular brand), all information required under the price disclosure requirements must have been provided for the whole of the data collection period for:

- the particular brand; or
- another listed brand with the same drug and manner of administration as the particular brand; or
- a combination of listed or delisted brands with the same drug and manner of administration as the particular brand so long as the information provided for each brand, when combined, results in information being provided for the whole of the data collection period.

The provision of data satisfying subregulation 37E(2) is a minimum data set for application of the price disclosure method. It is intended that if a minimum data set is disclosed in accordance with subregulation 37E(2), then the price disclosure method can be used for a particular brand even if data was not disclosed by all brands that have the same drug and manner of administration as the particular brand.

The new subregulation 37E(2) provides for a combination of brands to be used to make up the minimum data set, rather than the previous requirement that a single brand provide the minimum data set for the whole data collection period. The new requirement is consistent with a more comprehensive set of brand data being available.

The new subregulation 37E(3) is equivalent to the previous subregulation 37E(4), but makes specific provision for ***listed brands*** and ***delisted brands***. It provides that information provided by a responsible person under the price disclosure requirements may be disregarded for the price disclosure method if:

- for a listed brand - the information provided for a reporting period is incomplete; or
- for a delisted brand – the information provided for a reporting period while the brand was a listed brand is incomplete.

Item [9] – Paragraph 37EB(1)(c)

This item substitutes a new paragraph 37EB(1)(c) which provides that a single price disclosure cycle can have one or more reduction days.

It is expected that each price disclosure cycle will generally continue to have only one reduction day.

It is intended that although the main cycle with data collection periods ending 30 September 2012 has had a reduction day for some brands on 1 April 2013, it will have a further reduction day on 1 August 2013 for different brands. A second reduction day on this occasion means data not previously collected for delisted brands could be collected and used for determination of the weighted average disclosed prices for the further reduction day.

Item [10] – Subregulation 37EB(2) (notes 1 and 2)

This item substitutes new notes 1 and 2 for subregulation 37EB(2). The new notes are equivalent to the previous note 1. They provide updated references to regulations to work out the first disclosure cycle for a listed brand (regulations 37ED and 37F) and when a listed brand moves from a supplementary disclosure cycle to a main disclosure cycle (regulations 37EG and 37EH).

The previous note 2 was required for transitional provisions that have expired, and so the note has been repealed.

Item [11] – Subregulation 37EC(1)

This item substitutes a new subregulation 37EC(1) that is equivalent to the previous provision, but also make specific provision for delisted brands.

The new subregulation 37EC(1) provides that there are data collection periods for which information must be provided in compliance with price disclosure requirements for listed brands, and also for delisted brands, but only in relation to the period it was a listed brand.

Item [12] – Paragraph 37EC(2)(a)

This item changes the reference to "brand of a pharmaceutical item" in paragraph 37EC(2)(a) to "listed and delisted brand".

The change ensures the provision covers both a listed and a delisted brand, which is necessary because data collection periods apply for both listed and delisted brands.

Item [13] – Paragraphs 37EC(2)(b) and (c)

This item changes the references to "brands of a pharmaceutical item" in paragraphs 37EC(2)(b) and (c) to "listed and delisted brands"

The change ensures the provisions cover both listed and delisted brands because data collection periods apply for both listed and delisted brands.

Item [14] – Regulations 37EF

This item changes the references to "brand" in regulation 37EF to "listed brand".

This change ensures that only a listed brand is referred to because this provision concerns movement from one cycle into another cycle and only listed brands move to a new cycle. Delisted brands are only relevant for the cycle in which they are delisted.

Item [15] – Paragraph 37EG(1)(a) and subregulations 37EG(2) and (3)

This item changes the references to "brand" in paragraph 37EG(1)(a) and subregulations 37EG(2) and (3) to "listed brand".

This change ensures that only a listed brand is referred to because this provision concerns movement from one cycle into another cycle and only listed brands move to a new cycle. Delisted brands are only relevant for the cycle in which they are delisted.

Item [16] – Paragraph 37EH(1)(a) and subregulations 37EH(2) and (3)

This item changes the references to "brand" in paragraph 37EH(1)(a) and subregulations 37EH(2) and (3) to "listed brand".

This change ensures that only a listed brand is referred to because this provision concerns movement from one cycle into another cycle and only listed brands move to a new cycle. Delisted brands are only relevant for the cycle in which they are delisted.

Item [17] – Regulation 37F, heading

This item substitutes a new heading for regulation 37F, to refer specifically to both listed brands and delisted brands.

Item [18] – Subregulation 37F(1)

This item substitutes a new subregulation 37F(1).

Regulation 37F provides the manner in which price disclosure requirements for the first disclosure cycle and data collection period apply to a brand of a pharmaceutical item, if at the time it lists on the PBS there is another brand with the same drug and manner of administration already subject to price disclosure. The new brand joins the current price disclosure cycle or cycles for that drug/manner of administration.

The new subregulation 37F(1) provides for regulation 37F to apply to a listed brand where there are:

- other listed brands with the same drug and manner of administration already subject to price disclosure, and
- where there are no other such listed brands, but there is a delisted brand with the same drug and manner of administration that was subject to price disclosure, and the end of the data collection period for the delisted brand is after the start day for the relevant listed brand.

Item [19] – Paragraph 37F(3)(b)

This item makes clear that a new brand joins a prior disclosure cycle if the start day for the brand is before the reduction day for a listed brand with the same drug and manner of administration in the prior disclosure cycle.

Item [20] – Paragraph 37F(4)(b)

This item changes the expression "no other" brand in paragraph 37F(4)(b) to "no other listed" brand.

The new paragraph 37F(4)(b) refers only to another ***listed brand*** because subregulation 37F(4) concerns the allocation of certain new brands first becoming subject to price disclosure (relevant brand) to a particular data collection period, but only if there are no existing ***listed brands*** of the same pharmaceutical item subject to price disclosure on the day before, and the day, the new brand is subject to price disclosure. The provision has been amended to ensure it does not refer to there being no other ***delisted brands***. That is needed because subregulation 37F(4) specifically deals with situations when there are no existing ***listed brands*** of a pharmaceutical item subject to price disclosure.

Item [21] – At the end of regulation 37F

This item adds new subregulation 37F(5).

The new subregulation 37F(5) provides for 'other brand' in regulation 37F, to refer to both the listed brand or the delisted brand mentioned in subregulation 37F(1).

Item [22] – Subregulation 37FA(1)

This item changes the expression "brand of" a pharmaceutical item in subregulation 37FA(1) to "listed brand of" a pharmaceutical item.

The new paragraph 37FA(1) refers only to a ***listed brand*** of a pharmaceutical item because regulation 37FA concerns the method for working out an approved ex-manufacturer price to be used in a particular circumstance when a weighted average disclosed price needs to be worked out. No weighted average disclosed price is required for a ***delisted brand***, so ***delisted brands*** are not covered by the subregulation.

Item [23] – Subregulation 37FA(1) (notes 1 and 2)

This item repeals notes 1 and 2 to subregulation 37FA because they are no longer required. Item 4 of the Regulation inserts a definition for ***relevant day*** into Part 6A of the Principal Regulation.

Item [24] – Subparagraph 37FA(3)

This item substitutes a new subregulation 37FA(3). The new subregulation provides that the method for working out an approved ex-manufacturer price for a brand (relevant brand) on the ***relevant day*** for a prior disclosure cycle takes into account:

- administrative and statutory price reductions; and
- administrative price increases that would have occurred if the relevant brand had been a listed brand between the ***relevant day*** for the prior cycle and the day the relevant brand was listed.

This provision is relevant for working out an approved ex-manufacturer price when a new brand is allocated to a prior cycle by subregulation 37F(4).

The previous provision only takes account of statutory price reductions when working out the appropriate approved ex-manufacturer price on the ***relevant day***.

Item [25] – Subregulation 37FA(4)

This item inserts a new definition of ***price adjustment*** for the purposes of subregulation 37FA(3). The definition provides that a price adjustment means adjustments under:

- a price agreement or determination (administrative price changes); or
- Division 3A of Part VII of the Act (statutory price reductions).

This item inserts new definitions of ***price agreement*** and ***price determination***. These terms have the same meaning as in Part VII of the Act.

Item [26] – Subregulation 37FA(4), definition of price reduction provisions

This item repeals the definition of ***price reduction provisions*** because it is no longer referred to in the Principal Regulations.

Item [27] – Subregulation 37G(1)

This item changes the expression "the brands" in subregulation 37G(1) to "the listed brands".

The change ensures that subregulation 37G(1) referred only to listed brands. This is required because regulation 37G concerns the method for working out a weighted average disclosed price for a ***listed brand***. No weighted average disclosed price is required for a ***delisted brand***. However, the data of delisted brands is used in the price disclosure method to work out the weighted average disclosed price for a ***listed brand***.

Item [28] – At the end of subregulation 37G(5)

This item adds a note at the end of subregulation 37G(5) to refer the reader to the definition of ***adjusted volume*** in subregulation 37G(16).

Item [29] – Subregulation 37G(6)

This item repeals subregulation 37G(6). The previous subregulation provided that disclosed sales volume for the first month of a new listing was not taken into account when calculating the disclosed price.

The provision has been repealed, but the definition of adjusted volume provided for in this regulation provides the same effect.

Item [30] – Subregulations 37G(7) and (8)

This item substitutes new subregulations 37G(7) and (8).

Paragraph 37G(7)(a) provides the same effect as previous subregulation 37G(7).

Paragraph 37G(7)(b) provides that where the adjusted volume is zero or less, then the disclosed price for the brand would be zero. This is needed because the adjusted volume is the denominator in this mathematical formula. The provision provides clarity around a technical mathematical error that occurs when dividing by zero, and accords with current practice.

Paragraph 37G(8) provides the method for working out the price percentage difference for a brand. Paragraph 37G(8)(a) provides the same effect as previous subregulation 37G(8) for brands that were a listed brand on the relevant day.

Paragraph 37G(8)(b) provides the method for working out the price percentage difference where 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. In that case, the applicable approved ex-manufacturer price of the listed brand of the same pharmaceutical item as the delisted brand is used as a substitute for the applicable approved ex-manufacturer price for the delisted brand (which was not listed, and so had no approved ex-manufacturer price, on the

relevant day). The applicable approved ex-manufacturer price of the listed brand is the approved ex-manufacturer price for that brand on the relevant day (ie: the last day of the data collection period, or 1 October 2012 for the cycle with data collection period ending 30 September 2012).

The delisted brand's disclosed price is subtracted from the listed brand's approved ex-manufacturer price. The result is then divided by the listed brand's applicable approved ex-manufacturer price, and the result is expressed as a percentage to two decimal places.

Paragraph 37G(8)(c) provides the method for working out the price percentage difference where 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. In that case, a ***pharmaceutical item price*** is used as a substitute for the applicable approved ex-manufacturer price on the relevant day for the delisted brand. As there were no brands of the pharmaceutical item listed on the relevant day, a method will be used to work out a price. The pharmaceutical item price is defined, with a method for working out the price to be used in this provision, in subregulation 37G(16). It is a price that reflects what would have been the price for the brand if it had remained listed until the relevant day.

Item [31] – After subregulation 37G(11)

This item inserts a new subregulation 37G(11A) to provide, similar to subregulation 37G(7)(b), that where the sum of the adjusted volumes for the brands of a pharmaceutical item is zero or less, the weighted average percentage difference for the pharmaceutical item is zero.

This is needed because the sum of adjusted volume is the denominator in this mathematical formula. The provision provides clarity around a technical mathematical error that occurs when dividing by zero, and accords with current practice.

Item [32] – Subregulations 37G(13), (14) and (15)

This item substitutes new subregulations 37G(13), (14), (15) and (16).

New subregulation 37G(13) provides the same effect as the previous provision, except that it provides for the total adjusted volume for a pharmaceutical item to be used in the method for working out the weighted average percentage difference for every brand of every pharmaceutical item having the same drug and manner of administration.

The new subregulation 37G(13) also provides separately for calculations for pharmaceutical items:

- that have at least one listed brand on the relevant day - providing the same effect as the previous paragraph 37G(13)(a); and
- with delisted brands where there is no listed brand on the relevant day - providing for the ***pharmaceutical item price*** to be a substitute for the applicable approved ex-manufacturer price on the relevant day for the delisted brand(s) of a pharmaceutical item that has no listed brands, but otherwise providing the same effect as the previous paragraph 37G(13)(a) .

The previous provision used the PBS volume of the pharmaceutical item, as recorded by the Department, rather than the total adjusted volume. Although the mathematical method set out in the current subregulation is presented slightly differently due to redrafting, the effect is otherwise the same as the previous provision.

New subregulation 37G(14) provides, similarly to new paragraph 37G(7)(b) and subregulation 37G(11A), that where the sum of the amounts worked out under paragraph (d) for the pharmaceutical items with and without a listed brand on the relevant day 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.

This is needed because total adjusted volume is part of the denominator in this mathematical formula and can be zero or less leading to a result where the sum of the amounts in paragraph (d) can be zero or less. The provision provides clarity around a technical mathematical error that occurs when dividing by zero, and accords with current practice.

The new subregulation 37G(15) provides the same effect as previous subregulation 37G(14).

The new subregulation 37G(16) provides new definitions for regulation 37G.

New subregulation 37G(16) includes a definition of ***adjusted volume*** which is:

- for a listed brand – volume sold worked out as if pack sizes were equivalent to the pricing quantity on the relevant day minus any excluded adjusted volume
- for a delisted brand where there is a listed brand of the same pharmaceutical item on the relevant day - volume sold worked out as if pack sizes were equivalent to the pricing quantity of the listed brand on the relevant day minus any excluded adjusted volume
- for a delisted brand where there is no listed brand of the same pharmaceutical item on the relevant day - volume sold worked out as if pack sizes were equivalent to the pricing quantity of the last listed brand of the pharmaceutical item minus any excluded adjusted volume.

This makes changes to the previous definition of "adjusted volume" to provide for the adjusted volume for delisted brands. The current definition also provides for the exclusion of "***excluded adjusted volume***" when calculating adjusted volume and has the same result for listed brands as would have occurred previously after the operation of subregulation 37G(6).

Note 1 indicates that ***pricing quantity*** is defined in subsection 84AK(1) of the Act.

Note 2 indicates that the ***pricing quantity*** of a delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012 is set out in Division 2 of Part 8.

New subregulation 37G(16) has a definition of ***brand***, which includes both a ***listed brand***, and a ***delisted brand***.

This is important because although the method does not result in a weighted average disclosed price for delisted brands, the disclosed data for delisted brands is used in the method to arrive at the weighted average disclosed price for listed brands of pharmaceutical items.

New subregulation 37G(16) has a definition of ***excluded adjusted volume***. This makes provision for excluding the first month's volume from the method, where subregulation 37J(3) applies and the brand was not a listed brand immediately before the start day for the brand, or when subregulation 37J(4) applies, and has the same effect as previous subregulation 37G(6).

Note 1 indicates that the definition of ***pricing quantity*** is set out in subsection 84AK(1) of the Act.

Note 2 indicates that the ***pricing quantity*** of a delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012 is set out in Division 2 of Part 8.

New subregulation 37G(16) has a definition of ***last approved ex-manufacturer price***, which is the approved ex-manufacturer price of the last listed brand of a pharmaceutical item immediately before it delisted. This price is used for the purposes of calculating the pharmaceutical item price for a delisted brand where there is no listed brand of the same pharmaceutical item on the relevant day.

New subregulation 37G(16) has a definition of ***pharmaceutical item price***, which involves deducting any administrative or statutory price deductions that would have applied and adding any administrative price increases that would have applied to the "last approved ex-manufacturer price".

A Note indicates that the ***pharmaceutical item price*** of delisted brand where all brands of the pharmaceutical item were delisted before 1 October 2012 is set out in Division 2 of Part 8.

New subregulation 37G(16) has a definition of ***price adjustment***. The definition provides that a price adjustment means adjustments under:

- a price agreement or determination (administrative price changes); or
- Division 3A of Part VII of the Act (statutory price reductions).

New subregulation 37G(16) inserts new definitions of ***price agreement*** and ***price determination***. These terms have the same meaning as in Part VII of the Act.

New subregulation 37G(16) has a definition of ***total adjusted volume***, which means the sum of the adjusted volumes for all brands of a pharmaceutical item.

Item [33] – Subregulation 37H(1), note 1

This item removes the number from the note for subregulation 37GH(1) as a result of repeal of note 2.

Item [34] – Subregulation 37H(1), note 2

This item repeals note 2 for subregulation 37GH(1) because the transitional provision to which it refers have expired.

Item [35] – After subregulation 37H(1)

This item inserts new subregulation 37H(1A). It provides that the information required under subregulation 37H(1) for a listed brand, is required to be provided for supply of the delisted

brand for a reporting period, but only in relation to supplies made while the delisted brand was a listed brand.

Item [36] – Subregulation 37H(2)
This item changes the reference to subregulations 37G(3) or (6) to refer to subregulations 37J(3) or (4).

The change is required because subregulation 37G(6) has been removed, and in any event subregulations 37G(3) and (6) each refer to subregulations 37J(3) or (4). These provisions concern the reporting periods for a listed brand new to price disclosure. Item [37] and [38] – Subregulations 37H(3) and 37H(6)

These items change the references to "brand", when it first appears in subregulations 37H(3) and 37H(6), to "listed brand, including a delisted brand while it was a listed brand". These provisions concern the providing of incentives data.

Item [39] and [40] – At the end of subregulations 37HA(2) and 37I(2)

These items add a note at the end of subregulations 37HA(2) and 37I(2) indicating that, 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.

Regulation 37HA provides the requirements for who a responsible person is to provide information to for the purposes of the price disclosure provisions.

Regulation 37I provides for the manner and form in which information must be provided.

Item [41] – Subregulation 37J(1)

This item substitutes a new subregulation 37J(1), providing that the price disclosure information required to be provided must be provided within 6 weeks after:

- for a listed brand – the end of each reporting period;
- for a delisted brand – the end of the reporting period in which the brand delisted.

The responsibility for provision of required disclosure information continues after the responsible person ceases to be a responsible person for the brand or for all brands, and this provision clarifies when the information must be provided, for both listed and delisted brands.

Item [42] – Subregulations 37J(2), (5) and (6)

This item changes all references to "brand" in subregulations 37J(2), (5) and (6) to "listed brand".

The change provides for subregulations 37J(2), (5) and (6) to refer to reporting periods for ***listed brands***.

However, when read in conjunction with subregulation 37J(7), which provides for subregulations 37J(2) to (6) to apply to ***delisted brands***, the provisions cover both listed and delisted brands.

Items [43] and [45] – Subregulations 37J(6) and 37JA(6), note

These items repeal the notes for subregulations 37J(6) and 37JA(6).

The notes were required for transitional provisions that have expired.

Items [44] – At the end of regulation 37J

This item adds subregulation 37J(7), providing that subregulations 37J(2) to (6) apply to a delisted brand, but only until the end of the reporting period in which the brand was delisted. As a result, the reporting periods in regulation 37J cover both listed and delisted brands.

Item [46] – At the end of regulation 37JA

This item adds subregulation 37JA(7), providing that regulation 37JA applies to a delisted brand, but only until the end of the reporting period in which the brand was delisted. As a result, reporting periods in regulation 37JA cover both listed and delisted brands.

Item [47] – At the end of Part 8

This item adds a new Division to Part 8 of the Principal Regulations, which includes regulations 51, 52 and 53.

Regulation 51 provides that for the purposes of working out the weighted average disclosure price under regulation 37G, this new 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 the delisted brand was delisted before 1 October 2012 and all brands of the same pharmaceutical items as the delisted brand were delisted before 1 October 2012.

Where all brands of the pharmaceutical item delisted prior to 1 October 2012, these brands did not have an ***approved ex-manufacturer price*** or ***pricing quantity*** immediately prior to the last date that the last listed brand became a delisted brand. As such, the ***pharmaceutical item price*** and the ***adjusted volume*** are not able to be calculated in the usual way as described in subregulation 37G(16) and the ordinary method for calculating the weighted average disclosure price under regulation 37G cannot be applied.

This issue arises as the terms ‘approved ex-manufacturer price’ and ‘pricing quantity’ were introduced into the Act by amendment commencing 1 October 2012. Prior to that date listed brands had an ‘approved price to pharmacists’ and there was no concept of ‘pricing quantity’ articulated in the Act.

Note 1 makes it clear that pricing quantity is used for working out ***adjusted volume*** and ***excluded adjusted volume*** as defined in subregulation 37G(16).

Note 2 makes it clear that ***last approved ex-manufacturer price*** is defined in subregulation 37G(16).

Regulation 52 relates to delisted brands in the main disclosure cycle with relevant day 1 October 2012 fitting the profile explained in regulation 51.

Subregulation 52(1) sets out that for a delisted brand mentioned in an item of the table in Schedule 8, the amount specified for the delisted brand in column 5 of the table is the ***pharmaceutical item price***.

Subregulation 52(2) sets out that for a delisted brand mentioned in an item of the table in Schedule 8, the amount specified for the delisted brand in column 6 of the table is the ***pricing quantity***.

Subregulation 53(1) provides for a delisted brand mentioned in an item of the table in Schedule 9, the ***pharmaceutical item price*** is to be worked out by:

- under paragraph (a) taking the amount specified for the delisted brand in column 5 of Schedule 9 and deducting any amount that would have been deducted as a result of a price adjustment if the delisted brand was a listed brand in the period that began on commencement of the regulation and ended on the relevant day; and

- under paragraph (b) adding to the amount worked out under paragraph (a) any amount that would have been added to the amount specified for the delisted brand in column 5 of Schedule 9 under a price agreement or price determination if the delisted brand was a listed brand in the period that began on commencement of the regulation and ended on the relevant day.

Subregulation 53(2) sets out that for a delisted brand mentioned in an item of the table in Schedule 9, the amount specified for the delisted brand in column 6 is the ***pricing quantity***.

Subregulation 53(3) inserts a definition of ***price adjustment***. This definition provides that a price adjustment means adjustments under:

- a price agreement or determination (administrative price changes); or
- Division 3A of Part VII of the Act (statutory price reductions).

This subregulation also inserts new definitions of ***price agreement*** and ***price determination***. These terms have the same meaning as in Part VII of the Act.

Item [48] – At the end of the regulations

This item adds Schedule 8 which lists the pharmaceutical item price and pricing quantity for certain delisted brands with a main disclosure cycle relevant day of 1 October 2012 for the purposes of regulation 52.

This item also adds Schedule 9 which lists the pharmaceutical item price and pricing quantity for certain delisted brands with a main disclosure cycle relevant day of 30 September 2013 for the purposes of regulation 53.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

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

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Regulation

The *National Health (Pharmaceutical Benefits) Amendment Regulation 2013 (No. 1)* (the Regulation) amends Part 6A of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations), which makes provision in relation to price disclosure arrangements under the Pharmaceutical Benefits Scheme (PBS).

Part VII of the *National Health Act 1953* (the Act) is the legislative basis for the PBS by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians. Part VII, Division 3B of the Act deals with price disclosure. Price disclosure provides for the PBS 'approved ex-manufacturer price' of a 'brand of a pharmaceutical item' to be reduced on a reduction day in certain specified circumstances. The reduction is based on sales revenue, incentives and volume data disclosed by responsible persons (pharmaceutical companies) and occurs in accordance with the Act and the Principal Regulations.

The amendments reflect the reasons in the December 2012 *Sanofi-Aventis Australia Pty Limited v Minister for Health* Federal Court judgment (the judgment), which concerned the application of price disclosure provisions in the Act and Principal Regulations for certain brands removed or delisted from the PBS. The amendments make improvements to the collection of disclosed data, the method for working out potential price disclosure reductions and the days when reductions can occur.

Human rights implications

This Regulation engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

The price disclosure program progressively reduces the price of some PBS medicines which are subject to competition, ensuring better value for money from these medicines, which may also result in patients accessing these medicines at lower prices. These amendments provide improvements in the method for working out price disclosure reductions and the application of those reductions.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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