

EXPLANATORY STATEMENT

Select Legislative Instrument No. 60, 2014

National Health Act 1953
and

National Health Amendment (Simplified Price Disclosure) Act 2014

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

By authority of the Minister for Health

Authority

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.

Purpose

The regulation amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations), to simplify price disclosure arrangements under the Pharmaceutical Benefits Scheme (PBS).

The amendments are necessary to implement the Simplified Price Disclosure (SPD) policy, which was announced as part of the August 2013 Economic Statement, and to align with amendments to the Act made by the *National Health Amendment (Simplified Price Disclosure) Act 2014* (the Amending Act).

Background

The PBS operates under Part VII of the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. Price disclosure arrangements require pharmaceutical companies supplying PBS medicines which have multiple listed brands to disclose specified information about sales of those medicines. A weighted average price is calculated using the sales data over a data collection period and used as the basis for reductions in the PBS listed price.

By implementing SPD, the regulation will improve the operation of the PBS by streamlining current price disclosure arrangements. Under SPD, price reductions will occur sooner, and more frequently, after medicines become subject to market competition, and consumers will pay less for some PBS medicines.

Amendments

The regulation amends the Principal Regulations by:

- introducing six month data collection periods;
- using 1 April and 1 October as the days on which regular price reductions will occur;
- allowing a first data collection period longer than six months to ensure that at least six months of data is provided for a medicine with a drug or manner of administration new to price disclosure arrangements;
- refining the method to calculate the weighted average disclosed price by comparing sales data against an average PBS subsidised price;

- specifying additional reduction days of 1 December and 1 August, in case it becomes necessary to use these reduction days (for example, delay associated with legal proceedings); and
- simplifying drafting, including removing spent provisions, and providing for transition to the changed price disclosure arrangements.

Details of the regulation are set out in the Attachment.

Consultation

The Department of Health met with representatives from the pharmaceutical sector including industry, consumer, wholesaler and pharmacist groups in early December 2013 to discuss the legislative and other changes required to implement SPD. Representatives from the Consumers Health Forum, the Generic Medicines Industry Association, Medicines Australia, the National Pharmaceutical Services Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia attended.

In January 2014, further information setting out processes, key dates and transitional arrangements for SPD were provided to stakeholder groups and made available on the PBS website. Discussions with stakeholders continued through January, February and March 2014.

The regulation was drafted taking into consideration the discussions with stakeholders, including points made regarding certain steps of the price disclosure calculation. A confidential draft of the regulation was provided to nominated representatives of the seven stakeholder organisations who attended the December 2013 meeting.

In April and May 2014, the Department met separately with several stakeholder groups to explain the provisions in the draft regulation and receive comments. Comments from other stakeholders were received in writing.

Stakeholders considered that the draft regulation resolved many of the issues raised. They acknowledged that the method used to compare ex-manufacturer sales prices with PBS prices in calculating the weighted average disclosed price was greatly improved.

Communication with industry, pharmacy and other stakeholders will continue in the lead up to the first price reduction day on 1 October 2014. This will include updates to fact sheets and guidelines for PBS price disclosure.

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.

Authority: Section 140 of the
National Health Act 1953

Details of the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*

Section 1 - Name of regulation

This section provides that the title of the regulation is the *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014*.

Section 2 - Commencement

This section provides that the regulation commences 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 - 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

Item [1] – Subregulation 5(1)

This item provides that regulation definitions which are still needed for price disclosure are located in Regulation 5 (Interpretation). The definitions of ‘data collection period’, ‘delisted brand’, ‘incentive’, ‘price adjustment’ and ‘start day’ (with minor drafting simplifications) are relocated from Part 6A.

The item also provides definitions of ‘final day’, ‘initial month’, ‘last listed brand’, and ‘related brand’. These new terms simplify drafting in Part 6A. The new definition of ‘price sampling day’ is used when obtaining an ‘average approved ex-manufacturer price’ in proposed regulation 37J.

Definitions appearing in the Act, or relating to cycles which operated under the old price disclosure arrangements, no longer appear. For example, ‘listed brand’ appears in subsection 84(1) of the Act, ‘relevant day’ appears in subsection 99ADB(1) of the Act (as amended by the Amending Act) and definitions for supplementary disclosure cycles would no longer be required.

Item [2] – Part 6A (heading)

This item substitutes the heading to Part 6A to refer to ‘Price reduction and price disclosure’, replacing the current heading ‘Price reductions and price disclosures’.

Item [3] – Division 1 of Part 6A

This item repeals Division 1 of Part 6A. Division 1 contains definitions used in Part 6A that are relocated, where still relevant, to regulation 5 of the Principal Regulations.

This item also substitutes a new Division 1, with the heading ‘Division 1 – Price reduction’, and the insertion of new regulation 37A, to provide for 1 August and 1 December in any year to be prescribed reduction days.

The Act (as amended by the Amending Act) already expressly provides for 1 April and 1 October in any year to be price disclosure reduction days. The ability to prescribe additional reduction days was retained in paragraph 99ADH(2)(b) of the Act. Under the Fifth Community Pharmacy Agreement, 1 April, 1 August and 1 December are PBS price change points. The days 1 August and 1 December in any year, are prescribed in case it becomes necessary to use either of these instead of the usual reduction day (for example, delay associated with legal proceedings).

The actual reduction date for a medicine, for example, 1 October 2014, continues to be determined by the Minister under paragraph 99ADH(1)(aa) of the Act.

Regulation 37A replaces old regulation 37K referring to prescribed reduction days of 1 April, 1 August and 1 December.

Item [4] – Division 1A of Part 6A (heading)

This item repeals the heading ‘Division 1A – Price reductions’. The effect of this amendment is that current regulation 37B, which relates to outstanding 25 per cent price reductions under the Act, will continue to apply, but will be located in the Division headed ‘Division 1 – Price reduction’, following proposed regulation 37A.

Item [5] – Divisions 2 to 4 of Part 6A

This item reduces Divisions 2 to 4 of Part 6A to one Division 2 (Price Disclosure).

Division 2 – Price Disclosure

Subdivision 1 – Interpretation

37C Meaning of *data collection period*

New regulation 37C provides for the meaning of data collection period.

New regulation 37C replaces old regulations 37EA to 37F. This simplification is possible due to the creation of one ongoing 12 month administrative cycle, consisting of six month data collection periods, ending 31 March and 30 September each year, six months for data processing, publication of prices, and any administrative dispute resolution, and corresponding regular reduction days on 1 October and 1 April, respectively.

The old main, and supplementary A and B disclosure cycles are no longer needed. Regular six month data collection periods for medicines in price disclosure, run from:

- 1 April to 30 September; and
- 1 October to 31 March.

Start of first data collection period

Subregulation 37C(1) provides that the first data collection period for a brand starts on the brand’s start day.

The term ‘start day’ is defined in regulation 5 of the Principal Regulations (see item [1]) as the day on which the brand was first required to comply with price disclosure requirements under section 99ADD of the Act. This could occur because it is the day section 99ADD price disclosure requirements first apply to a drug, the manner of administration (MoA) for a drug, or the particular brand.

End of first data collection period

Subregulation 37C(2) deals with the situation where the drug/MoA is already subject to price disclosure requirements.

In this case, the first data collection period for the new brand ends when the data collection period for any brand with the same drug/MoA ends. This is 31 March or 30 September. That is, the new brand joins the disclosure cycle already underway for related brands. The first data collection period for the new brand would usually be six months or less, depending on the start date (date of PBS listing) of the new brand. However, across the drug/MoA, a minimum of six months of data would be provided by responsible persons. This treatment of new brands will have the same effect as old regulation 37F.

If the related brands that the new brand is joining are also in a first data collection period (see proposed subregulation 37C(3) below), the new brand's first data collection period may be more than six months.

Subregulation 37C(3) deals with the situation where the drug/MoA is not already subject to price disclosure requirements. The first data collection period ends:

- if the start day occurs between 2 April and 1 October – the next 31 March; or
- if the start day occurs between 2 October and 1 April – the next 30 September.

If a drug/MoA enters price disclosure on the following PBS price change points, the first data collection period for brands listed on the PBS on those dates will be:

- 1 April – six months;
- 1 August – eight months;
- 1 December – 10 months.

This ensures that at least six months data is provided by responsible persons for the drug/MoA.

Start and end of subsequent data collection periods

Subregulation 37C(4) deals with the start and end of subsequent data collection periods. After the first data collection period for a listed brand, each data collection period starts immediately after the end of the last data collection period, and ends on the next 31 March or 30 September, whichever is sooner.

Example 1 illustrates the operation of subregulations 37C(2), and 37C(4). This example is for a new brand with a drug/MoA for which related brands are already subject to price disclosure.

The example indicates that, if the new brand's start day is 1 July 2014, and the data collection period for a related brand ends on 30 September 2014, the first data collection period for the new brand will be 1 July 2014 to 30 September 2014 (three months, although across the drug/MoA there will be six months). Subsequent six month data collection periods will run from 1 October 2014 to 31 March 2015, 1 April 2015 to 30 September 2015, 1 October 2015 to 31 March 2016, and so on.

Examples 2 and 3 illustrate the operation of subregulations 37C(3) and 37C(4). These examples are for brands with a drug/MoA new to price disclosure.

Example 2 indicates that, if the brand's start day is 1 August 2014, the first data collection period will be 1 August 2014 to 31 March 2015 (eight months). Subsequent six month data collection periods will run from 1 April 2015 to 30 September 2015, 1 October 2015 to 31 March 2016, 1 April 2016 to 30 September 2016, and so on.

Example 3 indicates in a similar fashion that if a brand's start day is 1 December 2014, the first data collection period will be 1 December 2014 to 30 September 2015 (10 months). Subsequent periods will run from 1 October 2015 to 31 March 2016, 1 April 2016 to 30 September 2016, 1 October 2016 to 31 March 2017, and so on.

37D Meaning of *price sampling day*

The new definition 'price sampling day' is used when obtaining an 'average approved ex-manufacturer price' in regulation 37J.

The same 'average approved ex-manufacturer price' will be obtained for all brands (listed and delisted) with the same pharmaceutical item, as the proposed 'price sampling day' may be within the data collection period for another brand of the same pharmaceutical item (if it commenced earlier). The same 'average approved ex-manufacturer price' for all brands of the same pharmaceutical item will be the expected result as section 85C of the Act requires each brand of a pharmaceutical item to have the same 'approved ex-manufacturer price'.

37E Special rules for certain listed brands

Approved ex-manufacturer price on relevant day

Subregulation 37E(3) works out an approved ex-manufacturer price for a listed brand on the relevant day in situations where a brand lists on the PBS after the 'relevant day' and before reduction day, and there is no other listed brand of the same pharmaceutical item to rely upon for a flow-on price disclosure reduction (if any) under section 99ADHA of the Act.

The 'ten per cent test' in paragraph 99ADH(1)(c) of the Act provides that no price disclosure reduction for a listed brand will occur unless there is at least a ten per cent difference between the brand's 'applicable approved ex-manufacturer price' (that is, its 'approved ex-manufacturer price' on the relevant day) and the brand's determined 'weighted average disclosed price' (WADP).

The 'relevant day' is the day after the last day of the data collection period (subsection 99ADB(1) of the Act). The term 'applicable approved ex-manufacturer price' is defined in section 99ADB of the Act, and the term 'approved ex-manufacturer price' is defined in subsection 84(1) of the Act.

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

Subregulations 37E(4) and (5) provide for an average approved ex-manufacturer price to be worked out in situations where a brand lists on the PBS on or after the 'relevant day' and before reduction day, and there is no other listed brand of the same pharmaceutical item to rely upon for a flow-on price disclosure reduction (if any) under section 99ADHA of the Act. The average approved ex-manufacturer price is worked out in Step 3 for use in Step 11 of the Subdivision 2 weighted average disclosed price (WADP) method. The other steps in the WADP method would not be applicable as there are no data for the listed brand in the data collection period.

Subdivision 2 – Weighted average disclosed price

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

Subregulation 37F indicates that Subdivision 2 provides for the method to be used by the Minister (or delegate) in determining the weighted average disclosed price of a listed brand of a pharmaceutical item in respect of the data collection period (the WADP method).

The WADP method is the same as that prescribed in old regulation 37G, except for a proposed change to allow the calculation of the weighted average disclosed price by comparing sales data against an average PBS subsidised price, instead of the PBS subsidised price on the last day of the data collection period. There is also a change to provide for a maximum 99 per cent weighted average percentage difference across a drug/MoA, and a number of drafting simplifications.

Subregulation 37F(3) provides that when using the method, the Minister (or delegate) may disregard information provided under regulation 37T for a data collection period if it is incomplete. It has the same effect as old subregulation 37E(3).

37G Step 1 – Net revenue for brand

Regulation 37G relates to working out the net revenue for the listed brand for the data collection period. The net revenue is the revenue from sales of the listed brand for the data collection period, minus the value of any incentive given in relation to sales of the listed brand, and not including the listed brand's initial month.

This step has the same effect as Steps 1 and 2 in old regulations 37G(2), (3) and (4). The drafting has been simplified, in particular by making use of defined terms 'incentive, and 'initial month' see item [1].

The 'initial month' exclusion from the WADP method is the same as in the old regulations, and continues to apply only to the first month of data for a brand new to the PBS when it becomes subject to price disclosure requirements. A minimum of six months data is still provided by responsible persons across a drug/MoA. The effect is that the WADP method ignores discounting by the new entrants for one month.

Supplies to public hospitals would continue to be excluded from the information provided by a responsible person [see proposed regulation 37T], and therefore continue to be excluded from the WADP method.

37H Step 2 – Adjusted volume for brand

Regulation 37H relates to working out the adjusted volume of the listed brand sold for the data collection period.

The terms 'initial month' and 'final day' which are used in proposed regulation 37H are defined in regulation 5 of the Principal Regulations (see item [1]). The number of packs sold, and the separately disclosed initial month's number of packs sold, are all information disclosed by a responsible person in accordance with regulation 37T (old regulation 37H).

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

Regulation 37J relates to working out the average approved ex-manufacturer price of the listed brand for the data collection period. It is the sum of the approved ex-manufacturer price on each 'price sampling day' (the first day of every month of the data collection period), divided by the number price sampling days. When working out the average approved ex-manufacturer price for a listed brand, the approved ex-manufacturer price for any listed brand of the pharmaceutical item may be used, if necessary. This ensures that the average approved ex-manufacturer price for all brands of the same pharmaceutical item is the same regardless of a brand's start day or whether a brand is a delisted brand.

The term 'price sampling day' which is used in regulation 37J is defined in regulation 5 of the Principal Regulations (see item [1]).

Subregulation 37J(3) will provide for pricing quantity adjustment, where needed. If the pricing quantity on a price sampling day is different from the pricing quantity on the final

day, the approved ex-manufacturer price on the sampling day is adjusted so that the average approved ex-manufacturer price for the data collection period reflects the pricing quantity on the final day.

37K Step 4 – Disclosed price for brand

Regulation 37K relates to working out the disclosed price of the listed brand. The disclosed price is the amount worked out by dividing the net revenue for the listed brand (Step 1) by the adjusted volume for the listed brand (Step 2).

If the result is more than the average approved ex-manufacturer price for the listed brand (Step 3), the disclosed price will be the average approved ex-manufacturer price for the listed brand. This ‘capping’ will occur, where triggered, in Step 4 because the method is not interested in that portion of sales which may be above the average approved ex-manufacturer price. The result at subparagraph 37K(2)(b)(i) might be above the average approved ex-manufacturer price due, for example, to special patient contributions, sales direct to pharmacists or other variations relating to the reporting of sales.

Step 4 is a more targeted and refined approach to replace the approach in old subregulation 37G(9) (old Step 6). The PBS subsidy price used for comparison in the WADP method is an average approved ex-manufacturer price over the data collection period, instead of the approved ex-manufacturer price on the last day of the data collection period used in the old regulations.

The disclosed price is zero if the adjusted volume (Step 2) is zero or less.

37L Step 5 – Price percentage difference of brand

Regulation 37L relates to working out the price percentage difference of the listed brand. It is the disclosed price for the brand (Step 4) subtracted from the average approved ex-manufacturer price (Step 3), divided by the average approved ex-manufacturer price, and the result expressed as a percentage to two decimal places. This step has the same effect for listed brands as old Step 5 in old paragraph 37G(8)(a).

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

Regulation 37M provides for Steps 1 to 5 to be repeated for each brand of the same pharmaceutical item (including delisted brands).

Subregulation 37M(3) provides for pricing quantity adjustment, where needed, for delisted brands, based on the pricing quantity for another listed brand of the same pharmaceutical item. Where there is no remaining listed brand, the pricing quantity used for delisted brands is the pricing quantity of the last listed brand (the one that is delisted last).

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

Regulation 37N relates to working out the total adjusted volume of the brands of the pharmaceutical item by adding together the adjusted volume (Step 2) for each brand of the same pharmaceutical item.

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

Regulation 37P provides that to obtain the weighted average percentage difference of the brands of the pharmaceutical item, sum the adjusted volume (Step 2) multiplied by the price percentage difference (Step 5) for each brand of the same pharmaceutical item, and divide the result by the total adjusted volume (Step 7).

The weighted average percentage difference of the brands of the pharmaceutical item is zero if the total adjusted volume (Step 7) is zero or less.

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

Regulation 37Q provides for Steps 1 to 8 to be repeated for each pharmaceutical item with the same drug and MoA (including delisted brands). Subregulation 37Q(3) provides for pricing quantity adjustment, where needed, for delisted brands.

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

Regulation 37R relates to working out the weighted average percentage difference for the listed brand and all brands of all pharmaceutical items with the same drug and MoA.

The regulation provides that, to obtain the weighted average percentage difference (also known as the ‘WAPD’) which would apply across the drug/MoA, for each pharmaceutical item:

- (a) multiply the total adjusted volume (Step 7) by the average approved ex-manufacturer price for a brand of the pharmaceutical item (Step 3);
- (b) multiply that amount by the weighted average percentage difference of the brands of the pharmaceutical item (see Step 8);
- (c) add up the amounts obtained using (b) (that is, for all pharmaceutical items with same drug and MoA);
- (d) add up the amounts obtained using (a) (that is, for all pharmaceutical items with same drug and MoA);
- (e) divide the amount worked out in (c) by the amount worked out in (d)).

The weighted average percentage difference is zero if the amount worked out in (d) is zero or less.

The WAPD for the drug/MoA will be 99 per cent if the WAPD will otherwise be 99 per cent or more.

If the WAPD for the drug/MoA in Step 10 were to be equal to or greater than 100 per cent, the result in regulation 37S, Step 11, is then be a nil or negative weighted average disclosed price for a listed brand. This means that on reduction day the approved ex-manufacturer price for the listed brand will be nil or negative. To avoid this outcome, it is proposed that a maximum of 99 per cent applies for a WAPD across the drug/MoA in Step 10.

For consistency, the 99 per cent maximum applies to all WAPD results 99 per cent or greater at Step 10. For example, if the result would otherwise be 99.15 per cent, it would become 99 per cent.

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

Regulation 37S relates to working out to the weighted average disclosed price for a listed brand for the data collection period, which is the average approved ex-manufacturer price for the listed brand (Step 3) reduced by the weighted average percentage difference for the drug/MoA (Step 10).

Subregulation 37S(3) would provide for pricing quantity adjustment, if the pricing quantity of the listed brand on the final day is different from the pricing quantity on the relevant day. The pricing quantity adjustment ensures that the ‘ten per cent test’ in paragraph 99ADH(1)(c) of the Act will work appropriately and compare ‘like with like’ when applied.

A note refers to 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

Regulation 37T provides for price disclosure requirements.

Prescribed information

Subregulation 37T(2) is a simplified version of old regulation 37H. The content of information required remains the same, for example, supplies to a public hospital are not included.

Subregulation 37T(3) provides that, if information is provided under revenue from sales, the same information must not also be provided as an incentive.

Subregulation 37T(4) provides that number of packs sold, revenue from sales, and incentives, to the extent the information relates to the brand's initial month, must be provided separately. Item [1] provides that a definition of 'initial month' appears in regulation 5 of the Principal Regulations.

Subregulation 37T(5) provides that revenue from sales, and incentives, must be expressed in Australian dollars and rounded to the nearest whole dollar, rounding 50 cents upwards.

Consistent with the old regulations, the packs must fit the description of the brand (ie, drug, form, MoA, brand), and may equal a 'pack quantity' (subsection 84(1) of the Act), or any other pack size for the brand. The raw pack data is adjusted as if the size of the pack equals the pricing quantity, in all cases, to ensure that like is compared with like.

Prescribed person

Subregulation 37T(6) provides that the responsible person must provide the information to Australian Healthcare Associates Pty Ltd (ABN 82 072 790 848), or, if the responsible person receives written notice from the Department, the Secretary. Subregulation 37T(6), although simplified and more ambulatory, has the same effect as old regulation 37HA.

Prescribed manner and form

Subregulations 37T(7) and (8) mean that the responsible person must provide the information in a form approved by the Secretary. Subregulations 37T(7) and (8) have the same effect as old regulation 37I.

Prescribed times

Subregulation 37T(9) specifies the timeframes and deadlines for provision of information by a responsible person.

Subject to subregulation 37T(10), the responsible person is required to provide the information for each period:

- between 1 April and 30 September in a year – before the end of 11 November in that year; and
- between 1 October and the next 31 March – before the end of the next 12 May.

Subregulation 37T(10) provides that for the period between a brand's start day and the next 31 March or 30 September, whichever is the sooner, the responsible person will have to provide the information:

- if the start day happens between 1 April and 30 September in a year – before the end of 11 November in that year; or
- if the start day happens between 1 October and the next 31 March – before the end of the next 12 May.

Subregulation 37T(10) recognises that a brand is not required to report on information prior to its start day. It also requires that data for the period, which may be less than six months, between the brand's start day and the next 31 March or 30 September (whichever is sooner), be submitted as a batch on a one-off basis in a brand's first data collection period.

A responsible person for a delisted brand has an accrued obligation to provide information up to the date of delisting, on the next due date.

Subregulations 37T(9) and (10) is a simplified version of old regulations 37J and 37JA. A number of odd length reporting periods, and the separate concept of reporting periods, are no longer needed with the removal of supplementary cycles.

Item [6] – Division 1 of Part 8

This item repeals Division 1 Part 8, which is spent and no longer needed in the Principal Regulations.

Item [7] – Regulations 51 and 52

This item repeals regulations 51 and 52 of Division 2, Part 8, which are spent and no longer needed in the Principal Regulations.

Item [8] – At the end of Part 8

This item inserts a new Division 3 into Part 8 (Transitional provisions) for the regulation.

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

54 Application of Regulations

Subregulation 54(1) provides the Principal Regulations, as amended by the regulation, apply in relation to a data collection period that ends after 1 February 2014.

The following cycle continues to proceed under the old regulations (Expanded and Accelerated Price Disclosure 'EAPD'):

- 2014 supplementary disclosure cycle A (data collection period ends 31 January 2014, proposed reduction day 1 August 2014).

This application provision is consistent with item 3, Schedule 1 of the Amending Act, which provides for the Act amendments to apply to a data collection period ending on or after 1 February 2014. The reduction day of 1 August 2014 is prescribed under the old regulations, and the old 'relevant day' on the last day of the data collection period continues to apply to this EAPD cycle.

Subregulation 54(2) provides that regulation 54 applies subject to regulation 55.

55 Data collection periods

Subregulation 55(1) provides for new data collection period end dates for medicines in data collection periods which transition into Simplified Price Disclosure. The reduction day for medicines in a data collection period ending on:

- 31 March 2014 is 1 October 2014;
- 30 September 2014 is 1 April 2015; and
- 31 March 2015 is 1 October 2015.

Subregulation 55(2) provides that if a brand is a listed brand (at the time), the next data collection period for the brand starts on the day after the new data collection period end date. That is, if the data collection period ends:

- 31 March 2014, a new data collection period starts 1 April 2014;
- 30 September 2014, a new data collection period starts 1 October 2014; and
- 31 March 2015, a new data collection period starts 1 April 2015.

Under the old Regulations, responsible persons were required to report data up to 31 March 2014 by 12 May 2014. Once the regulations commence reporting occurs under the Principal Regulations as amended.

Subregulation 55(3) ensures, for the avoidance of doubt, that data provision due for a reporting period ending 31 March 2014 under the old Regulations for items 6, 7, or 8 for the beginning of the data collection period (an odd-length data batch, not a regular six months data batch), if it has not already occurred by the date the regulation commences, continues to have the due date of 12 May 2014, in accordance with the old Regulations.

Data for the data collection periods in the table to subregulation 55(1) either have already been due under the old Regulations, or, are reported in accordance with the new regulations.

Subregulation 55(4) provides for the insertion of two definitions for proposed regulation 55, being a definition of ‘brand’ (to include a listed or delisted brand, other than an exempt item), and a definition of ‘old Regulations’ (the Principal Regulations as in force immediately before the regulations).

56 Expiry of this Division

Regulation 56 would provide that Division 3 of Part 8 expires on 3 April 2016 as if it had been repealed by another regulation.

The reduction day for a data collection period ending 31 March 2015, the last shortened data collection period in the table in Division 3 of Part 8, is 1 October 2015. 3 April 2016 is after 1 April 2016, two reduction days after 1 October 2015.

The insertion of an expiry date for Division 3 of Part 8 would ensure that transitional Division 3 of Part 8 does not remain in the Principal Regulations indefinitely, adding to the complexity of the Principal Regulations.

Item [9] – Schedules 7 and 8

This item repeals Schedules 7 and 8 to the Principal Regulations, which relate to spent regulation 49 in Division 1, Part 8 (item [6] above) and spent regulation 52 (item [7] above).

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 (Price Disclosure) Regulation 2014

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 Legislative Instrument

The *National Health (Pharmaceutical Benefits) Amendment (Price Disclosure) Regulation 2014* amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) to align with amendments to the *National Health Act 1953* (the Act) made by the *National Health Amendment (Simplified Price Disclosure) Act 2014*.

The Pharmaceutical Benefits Scheme (PBS) operates under Part VII of the Act and provides Australians with reliable, timely, and affordable access to a wide range of medicines. Part VII, Division 3B of the Act deals with price disclosure, which ensures that the price at which the Government subsidises multiple-brand medicines more closely reflects the prices in the market.

The regulation amendments (together with the Act as amended) will improve the operation of the PBS by streamlining current price disclosure arrangements and delivering better value for money for PBS medicines. Price reductions will occur sooner and more frequently under the new arrangements. Consumers will pay less for some PBS medicines.

Human rights implications

This legislative instrument is compatible with Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights 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 assists with advancement of this human right by providing for subsidised access to medicines for Australians.

Conclusion

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

The Hon. Peter Dutton MP
Minister for Health