

EXPLANATORY STATEMENT
INSTRUMENT NUMBER PB 26 OF 2014

NATIONAL HEALTH ACT 1953

***National Health (Weighted average disclosed price – supplementary disclosure cycle A)
Determination 2014***

Authority

The *National Health Act 1953* (the Act) was amended by the *National Health Amendment (Simplified Price Disclosure) Act 2014* (the Amending Act) on 13 March 2014 to streamline the operation of price disclosure arrangements under the Act. However, those amendments only apply to a data collection period which ends on or after 1 February 2014 and the operation of the Act and *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations), as in force prior to the Amending Act commencing, continue for periods that end before 1 February 2014.

This legislative instrument is made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act and makes certain determinations relating to price disclosure for brands of pharmaceutical items in the supplementary disclosure cycle A with a data collection period ending 31 January 2014 (2014 Supplementary Cycle A).

Purpose

This legislative instrument determines a ‘weighted average disclosed price’ (WADP) for listed brands in the 2014 Supplementary Cycle A under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 August 2014 for listed brands in the 2014 Supplementary Cycle A with a data collection period ending at the end of 31 January 2014.

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (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 ‘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 collected from responsible persons (drug companies) and occurs in accordance with the Act and the Regulations.

A responsible person for a listed brand in Schedule 1 of this instrument, provided that the ‘approved ex-manufacturer price’ for the listed brand on 1 August 2014 would otherwise be more than the ‘adjusted approved ex-manufacturer price’, will receive a price reduction for the listed brand on and from 1 August 2014: subsections 99ADH(3) and (4).

Subsection 99ADB(4) – ‘weighted average disclosed price’

Subsection 99ADB(4) of the Act provides that the Minister may, by legislative instrument, determine the WADP of a listed brand in accordance with the Regulations.

Subsection 99ADB(6) of the Act provides that without limiting subsection 99ADB(4), the regulations may prescribe a method for determining the WADP for a listed brand. The method may take into account information (if any) that has been provided in compliance with the price disclosure requirements, and any other information, about the listed brand, other

listed or delisted brands of the same pharmaceutical item, and all listed or delisted brands of all pharmaceutical items that have the same drug and manner of administration as the pharmaceutical item.

Regulation 37G provides that the WADP is to be determined for a listed brand, and every other listed brand having the same subsection 85(2) listed drug and subsection 85(5) manner of administration, for the ‘data collection period’ for the listed brands in a ‘disclosure cycle’. ‘Disclosure cycle’ and ‘data collection period’ are defined in regulations 37EB and 37EC.

A brand is in the 2014 Supplementary Cycle A if:

- the price disclosure requirements first applied between 2 October 2012 and 1 February 2013 (inclusive) to a brand and no prior requirement to comply with the price disclosure requirements applies for any listed brand of pharmaceutical item with the same drug and manner of administration: sub-regulation 37ED(4); or
- the price disclosure requirements first apply to a brand on a day, and another brand with the same drug and manner of administration is in the 2014 Supplementary Cycle A: sub-regulation 37F(2) and (3).

A brand of an exempt item (section 84AH) is excluded from price disclosure and is not allocated to a price disclosure cycle: section 99ADA of the Act.

The price for new brands of existing pharmaceutical items listed on the PBS after 31 January 2014 will be reduced as a flow-on reduction under section 99ADHA on 1 August 2014 if at least one existing brand of the same pharmaceutical item is in Schedule 1. No WADP or reduction day is determined for these listed brands.

Paragraph 99ADH(1)(c) – unadjusted price reduction for listed brand must be at least 10% or no price reduction for listed brand on reduction day

Paragraph 99ADH(1)(c) of the Act (read with paragraph 99ADH(3)) provides that a price reduction for a listed brand will not occur unless the ‘unadjusted price reduction’ for a listed brand is at least 10%. The ‘unadjusted price reduction’ for a listed brand is defined in subsection 99ADB(1).

Listed brands where the unadjusted price reduction is calculated to be at least 10% appear in Schedule 1 to this instrument. Listed brands where the unadjusted price reduction is calculated as less than 10% appear in Schedule 2 to this instrument. Listed brands in Schedule 2 will not have a price disclosure related reduction on 1 August 2014.

Subsection 99ADB(4) – determining an ‘adjusted approved ex-manufacturer price’ for a listed brand in Schedule 1

Subsection 99ADB(7) provides that a subsection 99ADB(4) determination for a listed brand may include the ‘adjusted approved ex-manufacturer price’ for the listed brand.

It is the ‘adjusted approved ex-manufacturer price’ that is compared to the current ‘approved ex-manufacturer price’ of a listed brand that would otherwise apply on reduction day: subsections 99ADH(3) and (4) of the Act. The Explanatory Memorandum for the 1 December 2010 amendments to the Act explain that it is included in the subsection 99ADB(4) determination ‘for the assistance of companies and in the interests of transparency’.

In this instrument, where a WADP is determined for listed brands in Schedule 1, the ‘adjusted approved ex-manufacturer price’ is equal to the amount of the WADP. Since listed brands in Schedule 2 will not have a reduction on 1 August 2014, the ‘adjusted approved ex-manufacturer price’ is not included in Schedule 2.

Paragraph 99ADH(1)(aa) – determining a reduction day

A price disclosure reduction day must be one of the three reduction days prescribed in the Regulations, that is, either 1 April, 1 August or 1 December: subsection 99ADH(2) and Regulation 37K.

In order for a price reduction to occur for a listed brand, any one of the prescribed reduction days must be determined for the listed brand under paragraph 99ADH(1)(aa), or, the reduction must flow-on to the listed brand to match the reduction on the same date for another listed brand with the same pharmaceutical item, due to section 99ADHA of the Act.

Revocation

This instrument revokes previous determinations made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for the *National Health (Weighted average disclosed price – supplementary disclosure cycle A) Determination 2013* (PB 24 of 2013), the *National Health (Weighted average disclosed price – supplementary disclosure cycle B) Determination 2013* (PB 55 of 2013) and the *National Health (Weighted average disclosed price – main disclosure cycle) Determination 2013 (No.2)* (PB 82 of 2013) because listed brands in these cycles have had their reduction from these cycles. These brands moved into the 2015 main cycle.

Consultation

This instrument affects certain pharmaceutical companies with medicines listed on the PBS. Pharmaceutical companies were consulted in relation to the introduction of price disclosure requirements during both the policy development for introduction of price disclosure in 2007, and the implementation phases. Companies that had PBS listed medicines were also consulted during the development and implementation of the further PBS reforms of 2010 and pricing changes in 2012. This occurred through meetings with peak body organisations. Information on price disclosure was also disseminated through peak industry bodies, during meetings with the Price Disclosure Working Group and directly to companies through information sessions conducted by the Department in March 2011 and June 2012, and distribution of associated educational material. The relevant peak industry bodies included Medicines Australia, the Generic Medicines Industry Association, Consumers Health Forum, the Pharmacy Guild of Australia, the National Pharmaceutical Services Association and Australian Pharmaceutical Industries.

Pharmaceutical companies with a listed or delisted brand subject to the price disclosure requirements for 2014 Supplementary Cycle A were provided further information on the requirements and those companies disclosed information relevant to this determination directly to Australian Healthcare Associates Pty Ltd (AHA), known as the Price Disclosure Data Administrator (PDDA). AHA is prescribed in Regulation 37HA as the person to whom, in accordance with paragraph 99ADC(1)(a), a responsible person is to provide price disclosure information. The PDDA has provided responsible persons with an opportunity to check that the information disclosed to the PDDA has been translated correctly to PDDA data files. This was done prior to that data being used to apply the method set out in the Regulations required to arrive at the WADP for listed brands.

This instrument commences on the day after it is registered on the Federal Register of Legislative Instruments.

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

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011
National Health (Weighted average disclosed price – supplementary disclosure cycle A)
Determination 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

This *National Health (Weighted average disclosed price - supplementary disclosure cycle A) Determination 2014* makes certain determinations relating to price disclosure for listed brands of pharmaceutical items in the disclosure cycle with a data collection period ending 31 January 2014 (2014 Supplementary Cycle A).

Part VII of the *National Health Act 1953* (the Act) is the legislative basis for the Pharmaceutical Benefits Scheme (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 '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 collected from responsible persons (drug companies) and occurs in accordance with the Act and the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations).

This legislative instrument determines a 'weighted average disclosed price' (WADP) for listed brands in the 2014 Supplementary Cycle A under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 August 2014 for listed brands in the 2014 Supplementary Cycle A which are mentioned in Schedule 1 or 2 of this instrument.

A responsible person for a listed brand in Schedule 1 of this instrument, provided that the 'approved ex-manufacturer price' for the listed brand on 1 August 2014 would otherwise be more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 August 2014: subsections 99ADH(3) and (4) of the Act.

Human rights implications

This legislative instrument 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.

Conclusion

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

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