

**EXPLANATORY STATEMENT**  
**INSTRUMENT NUMBER PB 107 OF 2012**  
***NATIONAL HEALTH ACT 1953***

***National Health (Weighted average disclosed price – main disclosure cycle)***  
***Determination 2012***

**Authority**

This legislative instrument is made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the *National Health Act 1953* (the Act) and makes certain determinations relating to price disclosure for certain brands of pharmaceutical items in the main disclosure cycle with a data collection period ending 30 September 2012 (second main cycle).

**Purpose**

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 *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations).

A ‘brand of a pharmaceutical item’ (listed brand) is a pharmaceutical benefit which has a subsection 85(2) listed drug, subsection 85(3) form, subsection 85(5) manner of administration, and subsection 85(6) brand. The ‘approved ex-manufacturer price’ is the section 85AD agreed price or subsection 85B(2) determined price for a listed brand.

Since 1 December 2010 price disclosure requirements have applied to all non-exempt listed brands with a drug on the F2 formulary: sections 99ADD and 99ADA of the Act.

This legislative instrument determines a ‘weighted average disclosed price’ (WADP) for certain listed brands in the second main cycle under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 April 2013 for listed brands in the second main cycle with a data collection period ending at the end of 30 September 2012 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 April 2013 is more than the ‘adjusted approved ex-manufacturer price’, will receive a price reduction for the listed brand on and from 1 April 2013: subsections 99ADH(3) and (4).

The price for new brands of existing pharmaceutical items listed after 30 September 2012 will be reduced as a flow-on reduction under section 99ADHA on 1 April 2013 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.

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

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

Subsection 99ADB(6) 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 brands of the same pharmaceutical item, and all listed 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 listed brand of an exempt item (section 84AH) is excluded from price disclosure and is not allocated to a price disclosure cycle: section 99ADA. A brand to which s99ADHA applies is also excluded from the Regulation 37G method.

A listed brand is in the second main cycle if:

- the listed brand was in a previous main disclosure cycle: subregulation 37EF;
- the listed brand was in the first or second transitional disclosure cycles: transitional regulation 9 of the *National Health (Pharmaceutical Benefits) Amendment Regulations 2010 (No. 5)*;
- the price disclosure requirements first applied between 2 June 2011 and 1 October 2011 (inclusive) to a listed 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: subregulation 37ED(2)(a); or
- the price disclosure requirements first apply to a listed brand on a day, and another listed brand with the same drug and manner of administration is in the second main cycle: subregulation 37F(2) and (3).

It is expected that a further determination will be made in the future for listed brands in the second main cycle that are not covered by section 99ADHA of the Act and have no WADP determined in this instrument.

*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 reduction on 1 April 2013.

*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.

This price relates to the price reductions that will apply to the listed brand on reduction day. 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 April 2013, 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.

*Revocation*

This instrument revokes previous determinations made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act, for the first main disclosure cycle and the first and second transitional disclosure cycles because listed brands in these cycles have had their reduction from these cycles. These brands moved into the second 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 and implementation phases, and also during the development and implementation of the further PBS reforms of 2010 and pricing changes in 2012. This has occurred through meetings with both peak body organisations and individual companies. Information on this measure has been disseminated through peak industry bodies, during meetings with the Price Disclosure Working Group and direct to responsible persons through information sessions and educational material.

Pharmaceutical companies with a listed brand subject to the price disclosure requirements for main cycle 2 were provided further information on the requirements and have 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.

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 – main disclosure cycle) Determination 2012***

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 – main disclosure cycle) Determination 2012* makes certain determinations relating to price disclosure for certain brands of pharmaceutical items in the second main disclosure cycle with a data collection period ending 30 September 2012.

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 certain listed brands in the second main cycle under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 April 2013 for listed brands in the second main cycle with a data collection period ending at the end of 30 September 2012 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 April 2013 is more than the ‘adjusted approved ex-manufacturer price’, will receive a price reduction for the listed brand on and from 1 April 2013: subsections 99ADH(3) and (4).

#### **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. These reductions may also result in patients accessing these medicines at lower prices.

#### **Conclusion**

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

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