**EXPLANATORY STATEMENT**

**INSTRUMENT NUMBER PB 9 OF 2018**

***NATIONAL HEALTH ACT 1953***

***National Health (Weighted average disclosed price – April 2018 reduction day) Determination 2018***

## 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 brands of pharmaceutical items with a data collection period ending 30 September 2017 (2018 April Cycle).

## Purpose

This legislative instrument determines a 'weighted average disclosed price' (WADP) for listed brands of pharmaceutical items in the 2018 April Cycle under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 April 2018 for listed brands in the 2018 April Cycle with a data collection period ending on 30 September 2017 under paragraph 99ADH(1)(aa) of the Act.

Part VII of the Act is the legislative basis for the Pharmaceutical Benefits Scheme (PBS) through 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 2017* (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 April 2018 would otherwise be more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 April 2018: subsections 99ADH(3) and (4).

This legislative instrument is the fourth determination which provides for changes to the price disclosure arrangements for removal of 'originator brand' data from the calculation of the 'adjusted approved ex-manufacturer price'. Originator brands are determined by legislative instrument under subsection 99ADB(6B) of the Act. The current instrument is the *National Health (Originator Brand) Determination 2015 (PB 100 of 2015)*.

*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.

Part 7, Division 2, Subdivision B of the Regulations provides the method for determining a WADP for a listed brand of pharmaceutical item for a 'data collection period'. 'Data collection period' is defined in section 67 of the Regulations.

The Act and Regulations provide for brands that are part of the 2018 April Cycle. A brand is in the 2018 April Cycle if:

- the listed brand had a data collection period of six months or more on 30 September 2017;
- the brand was in the 2017 October Cycle; 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 2018 April Cycle.

A brand of an exempt item (section 84AH of the Act) is excluded from price disclosure and so does not have data collected or a determination for a reduction day: section 99ADA of the Act.

The price for new brands of existing pharmaceutical items listed on the PBS after 30 September 2017 will be reduced as a flow-on reduction under section 99ADHA on 1 April 2018 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 subsection 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 April 2018.

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

Subsection 99ADB(7) of the Act 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 what would otherwise be the current 'approved ex-manufacturer price' of a listed brand on reduction day: subsections 99ADH(3) and (4) of the Act. 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 2018, 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 1 April, 1 October, or another day prescribed under subsection 99ADH(2) of the Act. Section 66 of the Regulations provides that 1 August and 1 December are prescribed days.

In order for a price reduction to occur for a listed brand, one of the reduction days in the Act or prescribed in the Regulations 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.

This instrument determines 1 April 2018 as the reduction day for the relevant brands for the 2018 April Cycle.

**Revocation**

This instrument revokes the *National Health (Weighted average disclosed price – October 2017 reduction day) Determination 2017 (PB 44 of 2017)* (the previous determination) made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for the 2017 October Cycle (PB 44 of 2017) because listed brands in this cycle have had their reduction from this cycle.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* and subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act to revoke the previous determination. Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke amend or vary any such instrument.

**Consultation**

This instrument affects certain pharmaceutical companies with medicines listed on the PBS. Pharmaceutical companies with a listed or delisted brand subject to the price disclosure requirements for the 2018 April Cycle 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 by subsection 85(6) of the Regulations as the person to whom, in accordance with paragraph 99ADC(1)(a), a responsible person is to provide price disclosure information. The PDDA provided responsible persons with an opportunity to check that the information disclosed to the PDDA was translated correctly to PDDA data files. This was done prior to that data being used to apply the method set out in the Regulations to arrive at the WADP for listed brands.

Further consultation on this instrument was not considered necessary because affected pharmaceutical companies are provided with an opportunity to dispute any of the outcomes in the determination, through an industry agreed dispute resolution process. Any disputes are resolved through this mechanism prior the reduction day.

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

This instrument is a legislative instrument for the purposes of the *Legislation 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 – April 2018 reduction day) Determination 2018***

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 – April 2018 reduction day) Determination 2018* makes certain determinations relating to price disclosure for listed brands of pharmaceutical items with a data collection period ending 30 September 2017 (2018 April Cycle).

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 2017*.

This legislative instrument determines a 'weighted average disclosed price' for listed brands in the 2018 April Cycle under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 April 2018 for listed brands in the 2018 April Cycle which are mentioned in Schedule 1 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 2018 is more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 April 2018: 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 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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