EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 134 OF 2021

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2022 reduction day) Determination 2021

Authority

This legislative instrument is made under 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 2021 (2022 April Cycle).

This instrument repeals the previous determination made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for the 2021 October Cycle (PB 72 of 2021) pursuant to subsection 33(3) of the *Acts Interpretation Act 1901*.

Purpose

This legislative instrument determines a 'weighted average disclosed price' (WADP) for listed brands of pharmaceutical items in the 2022 April Cycle under subsection 99ADB(4) of the Act.

This legislative instrument also determines a reduction day of 1 April 2022 for listed brands in the 2022 April Cycle with a data collection period ending on 30 September 2021.

A provision-by-provision description of the Determination is contained in the Attachment.

Background

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 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, where the 'approved ex-manufacturer price' for the listed brand on 1 April 2022 will be more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 April 2022: 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.

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 2022 April Cycle. A brand is in the 2022 April Cycle if:

- the listed brand had a data collection period of six months or more on 30 September 2021; and
- a new brand is listed on the PBS for less than six months, during the data collection period, but is listed for a pharmaceutical item that is subject to price disclosure.

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 in accordance with section 99ADA of the Act. The current instrument of exempt items is the *National Health (Pharmaceutical Benefits Scheme - Exempt items - Section 84AH) Determination 2017* (PB 81 of 2017).

The price for new brands of existing pharmaceutical items listed on the PBS after 30 September 2021 will be reduced as a flow-on reduction under section 99ADHA on 1 April 2022 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 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:

- if the drug and manner of administration of the pharmaceutical item has been on F2 for less than 42 months – at least 10% (subparagraph 99ADH(1)(c)(i)); and
- if the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months – at least 30% (subparagraph 99ADH(1)(c)(ii)); and
- if the drug and manner of administration of the pharmaceutical item has been on F2 for at least 42 months and has had 2 consecutive price reductions under 99ADH(1)(c)(ii) in relation to the brand of pharmaceutical item – at least 10% (subparagraph 99ADH(1)(c)(iii)).

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% or at least 30%, as applicable, appear in Schedule 1 to this instrument. Listed brands where the respective unadjusted price reduction is calculated as less than 10% or less than 30%, as applicable, appear in Schedule 2 to this instrument. Listed brands in Schedule 2 will not have a price disclosure related reduction on 1 April 2022.

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 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. 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 2022, 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) of the Act, 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 2022 as the reduction day for the relevant brands for the 2022 April Cycle.

Repeal

This instrument repeals the previous determination made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for the 2021 October Cycle (PB 72 of 2021) because listed brands in this cycle have had their reduction from this cycle.

Consultation

This instrument affects certain pharmaceutical companies with medicines listed on the PBS. Pharmaceutical companies with a brand subject to the price disclosure requirements for the 2022 April Cycle disclosed information relevant to this determination directly to Australian Healthcare Associates Pty Ltd, known as the Price Disclosure Data Administrator (PDDA). The PDDA is prescribed in 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 than that set out above, 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 to the reduction day, with may necessitate further amendments to this instrument.

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

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.

Commencement

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

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

ATTACHMENT

DETAILS OF THE *NATIONAL HEALTH (WEIGHTED AVERAGE DISCLOSED PRICE – APRIL 2022 REDUCTION DAY) DETERMINATION 2021*

Section 1 Name

This section provides the name of this instrument is the *National Health (Weighted average disclosed price – April 2022 reduction day) Determination 2021*.

This instrument may also be cited as PB 134 of 2021.

Section 2 Commencement

This section provides that this instrument is to commence on the day it is registered.

Section 3 Repeal

This instrument repeals the previous determination made under subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for the 2021 October Cycle (PB 72 of 2021).

Section 4 Authority

This section provides that this instrument is made under the authority of subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act.

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.

Accordingly, the powers in subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act are relied upon to revoke the previous determination PB 72 of 2021 made pursuant to those powers.

Section 5 Definitions

This section defines certain terms used in the Instrument.

Section 6 Reduction Day

This instrument determines 1 April 2022 as the reduction day for the relevant brands for the 2022 April Cycle under 99ADH(1)(aa) the Act.

Section 7 Unadjusted price reduction is at least applicable percentage in Schedules 1 and 2

Under 99ADH(1)(c) of the Act, listed brands where the unadjusted price reduction is calculated to be at least 10% or at least 30%, as applicable, appear in Schedule 1 of this instrument. Brands listed in Schedule 1 are determined for a reduction on the reduction day.

Listed brands where the respective unadjusted price reduction is calculated as less than 10% or less than 30%, as applicable, appear in Schedule 2 to this instrument. Brands listed in Schedule 2 are not determined for a reduction on the reduction day.

Section 8 Weighted average disclosed price for brands of pharmaceutical items listed in Schedule 1

This section determines that for a brand of pharmaceutical item specified in column 2 in Schedule 1, the weighted average disclosed price in column 3 is the price that will take effect on the reduction day.

Section 9 Weighted average disclosed price for brands of pharmaceutical items listed in Schedule 2

As the unadjusted price reduction is calculated as less than 10% or less than 30% for a brand of pharmaceutical item specified in column 2 in Schedule 2, the weighted average disclosed price in column 3 is not the price that will take effect on the reduction day.

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 2022 reduction day) Determination 2021

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 Legislative Instrument is made pursuant to Part VII, Division 3B of *National Health Act 1953* (the Act) which relates to 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 under subsection 99ADB(4) of the Act and also determines a reduction day of 1 April 2022 for listed brands in the 2022 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 October 2021 is more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 April 2022: subsections 99ADH(3) and (4) of the Act.

Human rights implications

This Determination engages Article 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 that assists providing subsidised access to medicines for people. This is a positive and supportive step towards attaining the highest standard of health for all Australians. 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 Determination is compatible with human rights because it advances the protection of human rights.

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