EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 89 of 2023

*NATIONAL HEALTH ACT 1953*

*National Health (Weighted average disclosed price – October 2023 reduction day) Amendment Determination 2023*

# Authority

This legislative instrument is made pursuant to subsection 99ADB(4) of the *National Health Act 1953* (the Act), which provides that the Minister may, by legislative instrument, determine the weighted average disclosed price (WADP) of a brand of a pharmaceutical item (listed brand) in accordance with the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations).

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

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(4) for the medicines affected by this legislative instrument.

# Purpose

This legislative instrument amends the *National Health (Weighted average disclosed price – October 2023 reduction day) Determination 2023* (PB 53 of 2023) (the Principal Instrument) by:

* inserting into Schedule 1 WADPs for brands of pharmaceutical items containing:
	+ - pemetrexed, solution concentrate for I.V. infusion 1 g (as disodium) in 40 mL, injection;
		- pemetrexed, solution concentrate for I.V. infusion 500 mg (as disodium) in 20 mL, injection;
		- pemetrexed, solution concentrate for I.V. infusion 100 mg (as disodium) in 4 mL, injection;
* inserting into Schedule 2 WADPs for brands of pharmaceutical items containing:
	+ - methadone, oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL, oral;
		- methadone, oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL, oral;
		- naloxone, nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A), nasal;
* removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
	+ - ambrisentan, tablet 5 mg, oral;
		- ambrisentan, tablet 10 mg, oral;
		- fenofibrate, tablet 145 mg, oral;
		- fenofibrate, tablet 48 mg, oral; and
* revising WADPs in Schedule 1 for brands of pharmaceutical items containing:
	+ - aciclovir, eye ointment 30 mg per g, 4.5 g, application to the eye.

The Principal Instrument was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for brands of pharmaceutical items with a data collection period ending 31 March 2023 (2023 October cycle).

# Amendments

Revision of WADP determinations for brands of pharmaceutical items

Amendments to the Principal Instrument are being made following consideration of matters raised by Responsible Persons. These Amendments concern the determinations made in the Principal Instrument for brands of pharmaceutical items containing ambrisentan and fenofibrate, which will no longer take price disclosure reductions on 1 October 2023.

A review of determinations in response to matters raised by Responsible Persons revealed that WADP calculations had not taken into account disclosed data from the Responsible Person of the originator brand. Calculations for the WADPs including originator brand data set out in this amending determination had been calculated accordance with the Act and Regulations and were used for this revised determination, moving this drug from Schedule 1 to Schedule 2.

A review of determinations in response to matters raised by Responsible Persons revealed that a Responsible Person for a brand of fenofibrate had submitted incorrect data. Corrected data was resubmitted. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations, moving this drug from Schedule 1 to Schedule 2.

Insertion of WADP determinations for new brands of new pharmaceutical items

WADPs need to be determined for brands of new pharmaceutical items listing on the F2 formulary between 1 April 2023 and 30 September 2023 and where the drug is currently subject to price disclosure requirements.

There are six new pharmaceutical items that are included in this legislative instrument, brands of which have been listed on the PBS between the publication of the Principal Determination and this Amendment Determination. These new pharmaceutical items have been inserted into Schedule 2 with the exception of pemetrexed pharmaceutical items, which have been inserted into Schedule 1.

# Consultation

This instrument affects Responsible Persons for all brands of the drug and manner of administration aciclovir oral, ambrisentan oral, fenofibrate oral, methadone oral, naloxone nasal and pemetrexed injection.

A review of all determinations made in the Principal Instrument was conducted in accordance with the Price Disclosure Dispute Resolution Administrative Process, which provided Responsible Persons the opportunity to identify to the Department of Health and Aged Care any perceived issues with WADP determinations in the Principal Instrument. The Department conducted investigations to ensure the reductions were calculated correctly and that the reductions do not increase the risk of shortages in supply or unmet patient need. The reduction for one pharmaceutical item will change.

No additional consultation with experts was undertaken, as consultation with affected Responsible Persons drew on the knowledge of persons with relevant expertise.

This instrument commences on the day after registration. 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 – October 2023 reduction day) Amendment Determination 2023***

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 instrument amends the *National Health (Weighted average disclosed price – October 2023 reduction day) Determination 2023* (the Principal Instrument) to a) remove brands of pharmaceutical items which will no longer have a price reduction on reduction day from Schedule 1 and insert them in Schedule 2, b) update the WADP for brands of pharmaceutical items in Schedule 1, and c) update WADPs for brands of pharmaceutical items in Schedule 2.

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.

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 amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 October 2023 under the statutory provisions for price disclosure.

# 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.

**Adriana Platona**

**First Assistant Secretary**

**Technology Assessment and Access Division**

**Department of Health and Aged Care**