EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 22 of 2024

*NATIONAL HEALTH ACT 1953*

*National Health (Weighted average disclosed price – April 2024 reduction day) Amendment Determination 2024*

# 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 – April 2024 reduction day) Determination 2023* (PB 127 of 2023) (the Principal Instrument) by:

* inserting WADPs into Schedule 2 for brands of new pharmaceutical items that listed after publication of the Principal Instrument:
  + - Fluoxetine, Capsule 10 mg (Medreich) (S19A), Oral;
    - Hydromorphone, Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A), Oral;
    - Hydromorphone, Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (S19A) (Pharmascience), Oral;
    - Morphine, Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 1 mL (S19A), Oral;
    - Salbutamol, Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 (S19A), Inhalation.
* removing from Schedule 1 and inserting into Schedule 2 WADPs for brands of pharmaceutical items containing:
  + - Dorzolamide with timolol, Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL, Application to the Eye;
    - Levetiracetam , Oral solution 100 mg per mL, 300 mL, Oral;
    - Levetiracetam , Tablet 1 g, Oral;
    - Levetiracetam , Tablet 250 mg, Oral;
    - Levetiracetam , Tablet 500 mg, Oral;
    - Levonorgestrel with ethinylestradiol, Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets, Oral.
* inserting WADPs into Schedule 1 that were inadvertently omitted for brands of pharmaceutical items containing:
  + - Dasatinib, Tablet 100 mg, Oral;
    - Dasatinib, Tablet 20 mg, Oral;
    - Dasatinib, Tablet 50 mg, Oral;
    - Dasatinib, Tablet 70 mg, Oral;
    - Lenalidomide, Capsule 15 mg, Oral;
    - Lenalidomide, Capsule 25 mg, Oral;
    - Sunitinib, Capsule 25 mg, Oral;
    - Sunitinib, Capsule 37.5 mg, Oral;
    - Sunitinib, Capsule 50 mg, Oral.
* inserting WADPs into Schedule 2 that were inadvertently omitted for brands of pharmaceutical items containing:
  + - Ambrisentan, Tablet 10 mg, Oral;
    - Ambrisentan, Tablet 5 mg, Oral;
    - Dexamethasone, Intravitreal injection 700 micrograms, Implantation;
    - Dosulepin, Tablet containing dosulepin hydrochloride 75 mg, Oral;
    - Everolimus, Tablet 10 mg, Oral;
    - Hydrocortisone, Tablet 20 mg, Oral;
    - Levodopa with carbidopa, Intestinal gel containing levodopa 20 mg with carbidopa monohydrate 5 mg per mL, 100 mL, Intra-intestinal;
    - Norethisterone with ethinylestradiol, Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets, Oral;
    - Plerixafor, Injection 24 mg in 1.2 mL, Injection;
    - Pomalidomide, Capsule 3 mg, Oral;
    - Pomalidomide, Capsule 4 mg, Oral;
    - Tobramycin, Capsule containing powder for oral inhalation 28 mg (for use in podhaler), Inhalation by Mouth;
    - Trastuzumab, Solution for subcutaneous injection containing trastuzumab 600 mg in 5 mL, Injection.

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 on 30 September 2023 (2024 April 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 some brands of pharmaceutical items containing dorzolamide with timolol, levetiracetam, and levonorgestrel with ethinylestradiol, which will no longer take price disclosure reductions on 1 April 2024.

A review of determinations in response to matters raised by Responsible Persons concluded that the drugs/MoAs dorzolamide with timolol (application to the eye), all forms of levetiracetam (oral) and levonorgestrel with ethinylestradiol (oral) (*Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets*) are to be moved from Schedule 1 and inserted into Schedule 2.

The Amendments also concern the determinations made in the Principal Instrument for brands of pharmaceutical items containing dasatinib, lenalidomide, sunitinib, ambrisentan, dexamethasone, dosulepin, everolimus, hydrocortisone, levodopa with carbidopa, norethisterone with ethinylestradiol, plerixafor, pomalidomide, tobramycin, and trastuzumab, where the WADPs were inadvertently omitted. These WADPs have now been included.

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 October 2023 and 31 March 2024 and where the drug is currently subject to price disclosure requirements.

There are five 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.

# Consultation

This instrument affects Responsible Persons for all brands of the drugs and manner of administration (drugs/MoAs):

* Dorzolamide with timolol, Application to the Eye;
* Fluoxetine, Oral;
* Hydromorphone, Oral;
* Levetiracetam, Oral;
* Levonorgestrel with ethinylestradiol, Oral;
* Morphine, Oral;
* Salbutamol, Inhalation

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 reductions for six pharmaceutical items will change.

Responsible Persons for brands of pharmaceutical items where WADPs were inadvertently omitted in the Principal Instrument have been notified at the time of publication of Price Disclosure outcomes for the 2024 April Price Disclosure cycle on the PBS website.

In addition, Responsible Persons for brands of pharmaceutical items newly listed on the PBS were not consulted prior to this Instrument being made, as the determinations in this Instrument will not result in a price change for these products.

Australian Healthcare Associates Pty Ltd was consulted in an expert capacity and as the prescribed person for price disclosure requirements under section 85 of the *National Health (Pharmaceutical Benefits) Regulations 2017* (the Regulations). 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 – April 2024 reduction day) Amendment Determination 2024***

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 – April 2024 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) insert WADPs for brands of pharmaceutical items in Schedule 1, and c) insert 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 Regulations).

The amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 April 2024 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 prices 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**

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