EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 20 of 2022

*NATIONAL HEALTH ACT 1953*

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

# 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 2022 reduction day) Determination 2021* (PB 134 of 2021) (the Principal Instrument) by:

* Amending the form description for cabazitaxel to reflect editorial changes that will occur to the form description for cabazitaxel on 1 March 2022 in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* and also determining a WADP and reduction day for a new brand of cabazitaxel that will list on the PBS on 1 March 2022;
* removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
  + - fluticasone propionate with salmeterol, powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses, inhalation by mouth;
    - fluticasone propionate with salmeterol, powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses, inhalation by mouth;
    - fluticasone propionate with salmeterol, pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation), inhalation by mouth; and
    - fluticasone propionate with salmeterol, pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation), inhalation by mouth.
* inserting WADPs into Schedule 2 for brands of new pharmaceutical items that listed after publication of the Principal Instrument:
  + - chorionic gonadotrophin, injection set containing powder for injection 1,500 units, 3 and solvent 1 ml, 3 (s19A), injection;
    - chorionic gonadotrophin, powder for injection 5,000 units with solvent (s19A), injection;
    - ciclosporin, eye drops 1 mg per ml, single dose units 0.3 ml, 30, application to the eye;
    - etanercept, injection 50 mg in 1 ml single use dose-dispenser cartridges, 4, injection; and
    - levothyroxine, tablet containing 125 micrograms anhydrous levothyroxine sodium, oral.

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 30 September 2021 (2022 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 brands of the following drug and Manner of Administrations (MoA), fluticasone propionate with salmeterol, inhalation of mouth, which will no longer take a price disclosure reduction on 1 April 2022.

A review of determinations in response to matters raised by Responsible Persons confirmed that the correct unadjusted price reduction threshold for fluticasone propionate with salmeterol, inhalation of mouth as of the 2022 April cycle onwards is 30%, not 10% which was used to prepare calculations for this drug/MoA in the Principal Instrument. As the unadjusted price reductions for this drug/MoA’s pharmaceutical items are between 12.65% and 12.67%, below the 30% threshold, this drug/MoA will be moved from Schedule 1 to Schedule 2 and will not take a reduction on 1 April 2022.

Insertion of WADP determinations for new brands of new pharmaceutical items

WADPs need to be determined for brands of new pharmaceutical items that listed on the F2 formulary between 30 September 2021 and 31 March 2022. Examples are temporary PBS listing to cover medicine shortages, s19A temporary listings (chorionic gonadotrophin), and new forms of drugs (etanercept and levothyroxine).

There are six new pharmaceutical items that are included in this legislative instrument, as follows:

* cabazitaxel, concentrated injection 60 mg in 1.5 ml, with diluent, injection;
* chorionic gonadotrophin, injection set containing powder for injection 1,500 units, 3 and solvent 1 ml, 3 (s19A), injection;
* chorionic gonadotrophin, powder for injection 5,000 units with solvent (s19A), injection;
* ciclosporin, eye drops 1 mg per ml, single dose units 0.3 ml, 30, application to the eye;
* etanercept, injection 50 mg in 1 ml single use dose-dispenser cartridges, 4, injection; and
* levothyroxine, tablet containing 125 micrograms anhydrous levothyroxine sodium, oral.

The pharmaceutical item cabazitaxel, concentrated injection 60 mg (as acetone solvate) in 1.5 ml, with diluent, injection, will be removed from Schedule 1 and the equivalent cabazitaxel pharmaceutical item will be inserted into Schedule 1 as above.

# Consultation

This instrument affects Responsible Persons for all brands of the following drug/MoAs:

* cabazitaxel, injection;
* chorionic gonadotrophin, injection;
* ciclosporin, application to the eye;
* etanercept, injection;
* fluticasone propionate with salmeterol, inhalation of mouth; and
* levothyroxine, oral.

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 any perceived issues with WADP determinations in the Principal Instrument. The Department conducted investigations to ensure the reductions were calculated correctly. The reduction for only one item, fluticasone propionate with salmeterol, inhalation by mouth, will change.

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.

Responsible Persons for brands of the new cabazitaxel pharmaceutical item will be notified of their brands’ inclusion in Schedule 1, as the Principal Instrument reflects the WADP determination of these brands in Schedule 1 under the older cabazitaxel pharmaceutical item which has now been removed from the PBS, as identified earlier in this Explanatory Statement.

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 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 2022 reduction day) Amendment Determination 2022***

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 2022 reduction day) Determination 2021* (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, and b) insert WADPs for new brands of new pharmaceutical items.

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 April 2022 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.

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