EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 84 of 2022

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – October 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 – October 2022 reduction day) Determination 2022* (PB 61 of 2022) (the Principal Instrument) by:

- Inserting the WADP into Schedule 1 for the brand of new pharmaceutical item cabazitaxel, solution concentrate for I.V. infusion 60 mg in 3 mL, injection, that listed after publication of the Principal Instrument;
- removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
    - azithromycin, tablet 600 mg (as dihydrate), oral;
    - baclofen, intrathecal injection 40 mg in 20 mL, injection;
    - docetaxel, solution concentrate for I.V. infusion 80 mg in 8 mL, injection;
    - fentanyl, transdermal patch 16.5 mg, transdermal;
    - filgrastim, injection 120 micrograms in 0.2 mL single-use pre-filled syringe, injection;
    - filgrastim, injection 300 micrograms in 0.5 mL single-use pre-filled syringe, injection;
    - filgrastim, injection 480 micrograms in 0.5 mL single-use pre-filled syringe, injection;
    - naloxone, injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule, injection;
    - raloxifene, tablet containing raloxifene hydrochloride 60 mg, oral; and
    - rosuvastatin, tablet 40 mg (as calcium), oral.

- inserting WADPs into Schedule 2 for brands of new pharmaceutical items that listed after publication of the Principal Instrument:
    - abatacept, injection 125 mg in 1 mL single dose autoinjector, injection;
    - hydromorphone, oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL, oral;
    - imipramine, tablet containing imipramine hydrochloride 25 mg, oral; and
    - oxybutynin, tablet containing oxybutynin chloride 5 mg, 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 31 March 2022 (2022 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 azithromycin, baclofen, docetaxel, fentanyl, filgrastim, naloxone, raloxifene and rosuvastatin, which will no longer take a price disclosure reduction on 1 October 2022.

A review of determinations in response to matters raised by Responsible Persons revealed that:

- a Responsible Person for a brand of docetaxel 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; and
- there was an error in the methodology used in the WADP calculation report by the Price Disclosure Data Administrator. The revised calculations for the nine affected pharmaceutical items no longer satisfy the applicable 12.5% average unadjusted price reduction (UPR) test under section 99ADH of the Act, and the UPR now falls under the proper 30% threshold. The following nine pharmaceutical items will be moved from Schedule 1 to Schedule 2 and will not take a scheduled reduction:
    - azithromycin, tablet 600 mg (as dihydrate), oral;
    - baclofen, intrathecal injection 40 mg in 20 mL, injection;
    - fentanyl, transdermal patch 16.5 mg, transdermal;
    - filgrastim, injection 120 micrograms in 0.2 mL single-use pre-filled syringe, injection;
    - filgrastim, injection 300 micrograms in 0.5 mL single-use pre-filled syringe, injection;
    - filgrastim, injection 480 micrograms in 0.5 mL single-use pre-filled syringe, injection;
    - naloxone, injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule, injection;
    - raloxifene, tablet containing raloxifene hydrochloride 60 mg, oral; and
    - rosuvastatin, tablet 40 mg (as calcium), oral.

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 1 April 2022 and 30 September 2022. Examples are temporary PBS listing to cover medicine shortages, s19A temporary listings (abatacept, imipramine and oxybutynin), and new forms of drugs (cabazitaxel and hydromorphone).

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

- abatacept, 125 mg in 1 mL single dose autoinjector (s19A), injection;
- cabazitaxel, solution concentrate for I.V. infusion 60 mg in 3 mL, injection;
- hydromorphone, oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL, oral;
- imipramine, tablet containing imipramine hydrochloride 25 mg (s19A), oral; and
- oxybutynin, tablet containing oxybutynin chloride 5 mg (s19A), oral.

Consultation

This instrument affects Responsible Persons for all brands of the following drugs and manners of administration:

- abatacept, injection;
- azithromycin, oral;
- baclofen, injection;
- cabazitaxel, injection;
- docetaxel, injection;
- fentanyl, transdermal;
- filgrastim, injection;
- hydromorphone, oral;
- imipramine, oral;
- naloxone, injection;
- oxybutynin, oral;
- raloxifene, oral; and
- rosuvastatin, 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 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 ten pharmaceutical items will change.

In addition, Responsible Persons for brands of pharmaceutical items newly listed on the PBS were not consulted prior to the insertion of their brands in Schedule 2 of the Instrument, 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 have been informed of the inclusion of their brands in Schedule 1 of the Instrument.

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 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 – October 2022 reduction day) Determination 2022* (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 October 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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