EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 91 of 2024

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – October 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 – October 2024 reduction day) Determination 2024* (PB 67 of 2024) (the Principal Instrument) by:

- inserting into Schedule 2 WADPs for brands of pharmaceutical items containing:
  - amoxicillin with clavulanic acid, powder for oral suspension containing 125 mg amoxicillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 100 mL (S19A), oral;
  - azithromycin, powder for oral suspension 200 mg (as dihydrate) per 5 mL, 15 mL (S19A), oral;
  - medroxyprogesterone, injection containing medroxyprogesterone acetate 150 mg in 1 mL pre-filled syringe, injection;
  - octreotide, injection 50 micrograms (as acetate) in 1 mL (S19A), injection;
  - octreotide, injection 100 micrograms (as acetate) in 1 mL (S19A), injection;
  - prochlorperazine, tablet containing prochlorperazine maleate 5 mg (S19A), oral;
  - timolol, eye drops (gellan gum solution) 5 mg (as maleate) per mL, 2.5 mL (S19A), application to the eye; and
  - tiotropium, capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler), inhalation by mouth.

- removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
  - aciclovir, eye ointment 30 mg per g, 4.5 g, application to the eye;
  - atomoxetine, capsule 10 mg (as hydrochloride), oral;
  - atomoxetine, capsule 100 mg (as hydrochloride), oral;
  - atomoxetine, capsule 18 mg (as hydrochloride), oral;
  - atomoxetine, capsule 25 mg (as hydrochloride), oral;
  - atomoxetine, capsule 40 mg (as hydrochloride), oral;
  - atomoxetine, capsule 60 mg (as hydrochloride), oral;
  - atomoxetine, capsule 80 mg (as hydrochloride), oral;
  - deferasirox, tablet, dispersible, 125 mg, oral;
  - estradiol, transdermal gel 1 mg (as hemihydrate) in 1 g sachet, 28, transdermal;
  - gefitinib, tablet 250 mg, oral;
  - imatinib, tablet 600 mg (as mesilate), oral;
  - latanoprost with timolol, eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per ml, 2.5 ml, application to the eye;
  - metoclopramide, injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 ml, injection;
  - morphine, injection containing morphine sulfate pentahydrate 15 mg in 1 ml, injection;
  - morphine, injection containing morphine sulfate pentahydrate 30 mg in 1 ml, injection;
  - naloxone, injection containing naloxone hydrochloride 2 mg in 2 ml pre-filled syringe, injection;
  - palonosetron, injection 250 micrograms (as hydrochloride) in 5 ml, injection; and
  - pomalidomide, capsule 1 mg, oral
  - tenofovir, tablet containing tenofovir disoproxil fumarate 300 mg, oral
  - tobramycin, injection 80 mg (as sulfate) in 2 mL (without preservative), injection
- revising WADPs in Schedule 1 for brands of pharmaceutical items containing:
  - pirfenidone, tablet 267 mg, oral
  - pirfenidone, tablet 801 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 2024 (2024 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 aciclovir, atomoxetine, deferasirox, estradiol, gefitinib, latanoprost with timolol, metoclopramide, morphine, naloxone, palonosetron and tenofovir, which will no longer take price disclosure reductions on 1 October 2024.

A review of determinations in response to matters raised by Responsible Persons revealed that Responsible Persons for brands of pharmaceutical items containing gefitinib, pirfenidone

and tenofovir 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 gefitinib from Schedule 1 to Schedule 2, and revising the WADP for pirfenidone. For consistency with the policy intent of Section 82 of the *National Health (Pharmaceutical Benefits) Regulations 2017*, where price disclosure reductions do not apply in certain circumstances where there is little discounting and low sales volumes for brands of a pharmaceutical item, determinations made in the Principal Instrument for brands of pharmaceutical items containing imatinib, pomalidomide and tobramycin will also be amended, the affected brands will no longer take price disclosure reductions on 1 October 2024 consistent with the policy intent of the price disclosure requirements in the *National Health (Pharmaceutical Benefits) Regulations 2017.*

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 2024 and 30 September 2024 and where the drug is currently subject to price disclosure requirements.

There are eight 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 drug and manner of administration amoxicillin with clavulanic acid oral, azithromycin oral, medroxyprogesterone injection, octreotide injection, pirfenidone oral, prochlorperazine application to the eye, timolol application to the eye and tiotropium inhalation by mouth.

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.

To the extent that this instrument affects Responsible Persons for brands of the pharmaceutical items imatinib, tablet 600 mg (as mesilate), oral, pomalidomide, capsule 1 mg, oral and tobramycin, injection 80 mg (as sulfate) in 2 mL (without preservative), injection, it was considered that no consultation was necessary as the effect of the amendments is that a price reduction will not occur for those brands. The changed outcome for those brands should not increase the risk of shortages in supply or unmet patient need.

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

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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 2024 reduction day) Determination 2024* (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 appropriate and effective reductions, consistent with the intent of the price disclosure policies for prices for pharmaceutical benefits on 1 October 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 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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