

EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 23 of 2025

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2025 reduction day) Amendment Determination 2025

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 2025 reduction day) Determination 2024* (PB 146 of 2024) (the Principal Instrument) by:

- updating in Schedule 1 the form name for brands of pharmaceutical items containing:
 - esomeprazole, tablet (enteric coated) 20 mg (as magnesium), oral;
 - esomeprazole, tablet (enteric coated) 40 mg (as magnesium), oral;
 - varenicline, box containing 11 tablets 0.5 mg and 42 tablets 1 mg, oral;
 - varenicline, tablet 1 mg, oral.
- removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
 - 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;
 - buprenorphine, transdermal patch 10 mg, transdermal;
 - buprenorphine, transdermal patch 15 mg, transdermal;
 - buprenorphine, transdermal patch 20 mg, transdermal;
 - buprenorphine, transdermal patch 25 mg, transdermal;
 - buprenorphine, transdermal patch 30 mg, transdermal;

- buprenorphine, transdermal patch 40 mg, transdermal;
- buprenorphine, transdermal patch 5 mg, transdermal;
- bisacodyl, tablet 5 mg, oral;
- cyclophosphamide, powder for injection 1 g (anhydrous), injection;
- erythromycin, capsule 250 mg (containing enteric coated pellets), oral;
- ezetimibe and rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium), oral;
- ezetimibe and rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium), oral;
- ezetimibe and rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium), oral;
- 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, pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation), inhalation by mouth;
- hydromorphone, injection containing hydromorphone hydrochloride 10 mg in 1 ml, injection;
- hydromorphone, injection containing hydromorphone hydrochloride 2 mg in 1 ml, injection.
- hydromorphone, tablet containing hydromorphone hydrochloride 2 mg, oral;
- hydromorphone, tablet containing hydromorphone hydrochloride 4 mg, oral;
- hydromorphone, tablet containing hydromorphone hydrochloride 8 mg, oral;
- infliximab, solution for injection 120 mg in 1 mL pre-filled pen, injection;
- 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 10 mg in 1 ml, injection;
- norethisterone with ethinylestradiol, pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets, oral;
- norethisterone with ethinylestradiol, pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets, oral;
- palonosetron, injection 250 micrograms (as hydrochloride) in 5 ml, injection;
- riluzole, oral suspension 50 mg per 10 ml, 300 ml, oral;
- tenofovir, tablet containing tenofovir disoproxil fumarate 300 mg, oral;
- trastuzumab, powder for I.V. infusion 150 mg, injection
- trastuzumab, powder for I.V. infusion 440 mg with diluent, injection.
- inserting into Schedule 2 WADPs for brands of pharmaceutical items containing:
 - acarbose, tablet 100 mg (S19A), oral;
 - acarbose, tablet 50 mg (S19A), oral;
 - estradiol, transdermal gel (pump pack) 750 micrograms (as hemihydrate) per 1.25 g dose, 64 doses, transdermal;
 - estradiol, transdermal gel 500 micrograms in 0.5 g sachet, 28, transdermal;
 - estradiol, transdermal patches 1.17 mg, 24 (S19A), transdermal;
 - estradiol, transdermal patches 1.56 mg, 24 (S19A), transdermal;

- estradiol, transdermal patches 1.56 mg, 24 (Sandoz) (S19A), transdermal;
- estradiol, transdermal patches 390 micrograms, 24 (S19A), transdermal;
- estradiol, transdermal patches 585 micrograms, 24 (S19A), transdermal;
- estradiol, transdermal patches 780 micrograms, 24 (S19A), transdermal;
- ezetimibe, tablet 10 mg (S19A), oral;
- lenalidomide, capsule 20 mg, oral;
- morphine, tablet containing morphine sulfate pentahydrate 30 mg, oral;
- risperidone, I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 100 mg and 1 pre-filled syringe diluent 490 microlitres, injection;
- risperidone, I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 75 mg and 1 pre-filled syringe diluent 383 microlitres, injection;
- tenofovir with emtricitabine, tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg (S19A), oral;
- timolol, eye drops (gellan gum solution) 5 mg (as maleate) per ml, 2.5 ml - (Timoptol-LA) (S19A), application to the eye;
- timolol, eye drops 5 mg (as maleate) per ml, 5 ml (S19A), application to the eye;
- ursodeoxycholic acid, capsule 500 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 30 September 2024 (2025 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 pharmaceutical items containing atomoxetine, bisacodyl, buprenorphine, cyclophosphamide, erythromycin, ezetimibe and rosuvastatin, fentanyl, fluticasone propionate with salmeterol, hydromorphone, infliximab, imatinib, latanoprost with timolol, metoclopramide, morphine, norethisterone with ethinylestradiol, palonosetron, riluzole, tenofovir and trastuzumab, which will no longer take price disclosure reductions on 1 April 2025.

A review of determinations in response to matters raised by Responsible Persons revealed that Responsible Persons for brands of pharmaceutical items containing fluticasone propionate with salmeterol and hydromorphone 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, and moving fluticasone propionate with salmeterol and hydromorphone from Schedule 1 to Schedule 2. For consistency with the policy intent of Section 82 of the Regulations, 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 fentanyl, hydromorphone and imatinib will also be amended, and the affected brands will no longer take price disclosure reductions on 1 April 2025 consistent with the policy intent of the price disclosure requirements in the Regulations.

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 18 new pharmaceutical items which have been listed after 30 September and before the reduction day of 1 April 2025 that are included in this legislative instrument. 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 atomoxetine, bisacodyl, buprenorphine, cyclophosphamide, erythromycin, ezetimibe and rosuvastatin, fentanyl, fluticasone propionate with salmeterol, hydromorphone, imatinib, infliximab, latanoprost with timolol, metoclopramide, morphine, norethisterone with ethinylestradiol, palonosetron, riluzole, tenofovir, and trastuzumab.

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 two pharmaceutical items will change.

Consultation with medical officers employed by the Department was undertaken for some of the disputed drugs. Consultation with affected Responsible Persons also drew on the knowledge of persons with relevant expertise.

To the extent that this instrument affects Responsible Persons for brands of the drugs atomoxetine, bisacodyl, buprenorphine, cyclophosphamide, erythromycin, ezetimibe and rosuvastatin, fentanyl, fluticasone propionate with salmeterol, hydromorphone, imatinib, infliximab, latanoprost with timolol, metoclopramide, morphine, norethisterone with ethinylestradiol, palonosetron, riluzole, tenofovir, and trastuzumab, 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
National Health (Weighted average disclosed price – April 2025 reduction day)
Amendment Determination 2025

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 2025 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 Regulations.

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 April 2025 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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