

EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 86 OF 2021

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – October 2021 reduction day) Amendment Determination 2021

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.

Purpose

This legislative instrument amends the *National Health (Weighted average disclosed price – October 2021 reduction day) Determination 2021* (PB 72 of 2021) (the Principal Instrument) by:

- removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
 - pegfilgrastim, injection 6 mg in 0.6 mL single use pre-filled syringe, injection;
 - clonidine, tablet containing clonidine hydrochloride 100 micrograms, oral and;
 - clonidine, tablet containing clonidine hydrochloride 150 micrograms, oral.
- inserting WADPs for brands of new pharmaceutical items that listed after publication of the Principle Instrument:
 - aciclovir, eye ointment 30 mg per g, 4.5 g, application to the eye;
 - adrenaline (epinephrine), injection:
 - I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector;
 - Solution for injection 1 mg (as tartrate) in 1 mL (1 in 1,000);
 - hydromorphone, oral solution containing hydromorphone hydrochloride 1 mg per mL, 473 mL, oral;
 - imipramine, tablet containing imipramine hydrochloride 10 mg USP, oral;
 - infliximab, injection:
 - Solution for injection 120 mg in 1 mL pre-filled pen;
 - Solution for injection 120 mg in 1 mL pre-filled syringe;
 - paraffin, eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free), application to the eye; and
 - tenofovir with emtricitabine, tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 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 2021 (2021 October cycle).

Amendments

Revision of WADP determinations for brands of Pharmaceutical Items

Amendments are being made following consideration of matters raised by Responsible Persons concerning the determinations in the Principal Instrument for brands of pharmaceutical items containing clonidine and pegfilgrastim.

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

- Responsible Persons for brands of clonidine 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
- pegfilgrastim will not take a scheduled reduction due to the correct threshold for its calculations being 30 per cent, moving the drug from Schedule 1 to Schedule 2.

Insertion of WADP determinations for new brands of new pharmaceutical items

WADPs need to be determined for new pharmaceutical items that listed on the F2 formulary between 1 April 2021 and 30 September 2021. Examples are s19A temporary listings (adrenaline (epinephrine), imipramine), new forms of drugs (aciclovir, adrenaline (epinephrine), infliximab, paraffin, tenofovir with emtricitabine), and formerly exempt items (hydromorphone).

There are nine new pharmaceutical items that are included in this amending instrument, as follows:

- aciclovir, eye ointment 30 mg per g, 4.5 g, application to the eye;
- adrenaline (epinephrine), injection:
 - I.M. injection 500 micrograms in 0.3 mL single dose syringe auto-injector;
 - solution for injection 1 mg (as tartrate) in 1 mL (1 in 1,000);
- hydromorphone, oral solution containing hydromorphone hydrochloride 1 mg per mL, 473 mL, oral;
- imipramine, tablet containing imipramine hydrochloride 10 mg USP, oral;
- infliximab, injection:
 - solution for injection 120 mg in 1 mL pre-filled pen;
 - solution for injection 120 mg in 1 mL pre-filled syringe;
- paraffin, eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free), application to the eye; and
- tenofovir with emtricitabine, tablet containing tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg, oral.

Basis for amendments

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 amending instrument.

Consultation

This instrument affects companies that are Responsible Persons for all brands of all pharmaceutical items containing clonidine and pegfilgrastim.

All of the affected Responsible Persons were consulted about the amendments. 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 it is registered on the Federal Register of Legislation. 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 2021 reduction day)
Amendment Determination 2021

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 2021 reduction day) Determination 2021* (the Principal Instrument) to: a) amend prices of brands of pharmaceutical items which continue to have a price reduction on reduction day, b) remove brands of pharmaceutical items which will no longer have a price reduction on reduction day, and c) insert prices 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 2021 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.

Adriana Platona
First Assistant Secretary
Technology Assessment and Access Division
Department of Health