

EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 18 OF 2018

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2018 reduction day) Amendment Determination 2018 (No.1)

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 – April 2018 reduction day) Determination 2018* (PB 9 of 2018) (the Principal Instrument) by re-allocating brands of pharmaceutical items and their corresponding WADPs that no longer meet the criteria for a price reduction under subsection 99ADH(1)(c) of the Act.

All brands of all pharmaceutical items containing the following drugs and manners of administration are affected (except where a particular pharmaceutical item is specified; only brands of that pharmaceutical item are affected):

- alendronic acid for oral administration;
- amoxicillin with clavulanic acid for oral administration;
- ampicillin for administration by injection;
- anastrozole for oral administration;
- azathioprine for oral administration;
- azithromycin, tablet 500 mg (as dihydrate), oral;
- bleomycin for administration by injection;
- candesartan for oral administration;
- candesartan with hydrochlorothiazide for oral administration;
- carvedilol for oral administration;
- ceftriaxone for administration by injection;
- cephazolin for administration by injection;
- ciprofloxacin for oral administration;
- clindamycin for oral administration;
- dexamethasone, intravitreal injection 700 micrograms, injection;
- escitalopram for oral administration;
- fentanyl for transdermal administration;
- filgrastim for administration by injection;
- frusemide for administration by injection;
- lamivudine, tablet 100 mg, oral;

- lamivudine, tablet 150 mg, oral;
- lamivudine, tablet 300 mg, oral;
- meloxicam for oral administration;
- methylprednisolone, powder for injection 40 mg (as sodium succinate) with diluent, injection;
- montelukast for oral administration;
- naltrexone for oral administration;
- olanzapine for oral administration;
- oxaliplatin for administration by injection;
- pramipexole for oral administration;
- risedronic acid for oral administration;
- risperidone, tablet 0.5 mg, oral;
- rosuvastatin for oral administration;
- tacrolimus for oral administration;
- telmisartan with hydrochlorothiazide for oral administration;
- terbinafine for oral administration;
- valproic acid for oral administration; and
- vinorelbine for administration by injection.

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 2017 (2018 April cycle).

Amendments

Amendments are being made following commencement of changes to the Act by the *National Health Amendment (Pharmaceutical Benefits—Budget and Other Measures) Act 2017*. Amendments included changes to the price disclosure requirements under Division 3B of the Act.

This amending instrument re-allocates brands of pharmaceutical items from Schedule 1 to Schedule 2 of the Principal Instrument because they no longer meet the criteria for a price reduction on the reduction day.

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 the following drugs and manners of administration (except where a particular pharmaceutical item is specified; only Responsible Persons for brands of that pharmaceutical item are affected):

- alendronic acid for oral administration;
- amoxicillin with clavulanic acid for oral administration;
- ampicillin for administration by injection;
- anastrozole for oral administration;
- azathioprine for oral administration;
- azithromycin, tablet 500 mg (as dihydrate), oral;
- bleomycin for administration by injection;

- candesartan for oral administration;
- candesartan with hydrochlorothiazide for oral administration;
- carvedilol for oral administration;
- ceftriaxone for administration by injection;
- cephazolin for administration by injection;
- ciprofloxacin for oral administration;
- clindamycin for oral administration;
- dexamethasone, intravitreal injection 700 micrograms, injection;
- escitalopram for oral administration;
- fentanyl for transdermal administration;
- filgrastim for administration by injection;
- frusemide for administration by injection;
- lamivudine, tablet 100 mg, oral;
- lamivudine, tablet 150 mg, oral;
- lamivudine, tablet 300 mg, oral;
- meloxicam for oral administration;
- methylprednisolone, powder for injection 40 mg (as sodium succinate) with diluent, injection;
- montelukast for oral administration;
- naltrexone for oral administration;
- olanzapine for oral administration;
- oxaliplatin for administration by injection;
- pramipexole for oral administration;
- risedronic acid for oral administration;
- risperidone, tablet 0.5 mg, oral;
- rosuvastatin for oral administration;
- tacrolimus for oral administration;
- telmisartan with hydrochlorothiazide for oral administration;
- terbinafine for oral administration;
- valproic acid for oral administration; and
- vinorelbine for administration by injection.

All of the affected companies were notified that amendments would occur upon commencement of the *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018*. No concerns were expressed.

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 – April 2018 reduction day)
Amendment Determination 2018 (No.1)

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 2018 reduction day) Determination 2018* (the Principal Instrument) by re-allocating brands of pharmaceutical items that no longer meet criteria for a price reduction on reduction day following amendments by the *National Health Amendment (Pharmaceutical Benefits – Budget and Other Measures) Act 2018* to the price disclosure requirements under Division 3B of the *National Health Act 1953* (the Act).

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.

Part VII, Division 3B of the Act deals with price disclosure. 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 correct and effective reductions in prices for pharmaceutical benefits on 1 April 2018 under the statutory provisions for price disclosure.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 which assists with advancement of this human right by providing for subsidised access by patients to medicines.

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 Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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