

## EXPLANATORY STATEMENT

### INSTRUMENT NUMBER PB 79 OF 2018

#### *NATIONAL HEALTH ACT 1953*

#### *National Health (Weighted average disclosed price – October 2018 reduction day) Amendment Determination 2018*

#### **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 2018 reduction day) Determination 2018* (PB 42 of 2018) (the Principal Instrument) by:

- amending the WADPs for brands of pharmaceutical items containing granisetron for administration by injection (granisetron);
- inserting a WADP for the first new brand of new pharmaceutical items containing methotrexate for administration by injection (methotrexate) and zoledronic acid for administration by injection (zoledronic acid).

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 2018 (2018 October cycle).

#### **Amendments**

##### *Granisetron*

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 granisetron. A review of determinations in response to matters raised by responsible persons revealed that incorrect data had been submitted by a responsible person. Corrected data was submitted by some responsible persons for certain brands containing granisetron. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations.

##### *Insertion of WADP determinations for New Brands of New Pharmaceutical Items*

A WADP is required to be determined for new brands of pharmaceutical items listing between 31 March 2018 and 30 September 2018 that have no other existing brand of the same pharmaceutical item (including a single brand pharmaceutical item where the brand or pharmaceutical item changes, or where all existing brands change).

There are six brands of six new pharmaceutical items that are included in this amending instrument, as follows:

- the Trexject<sup>®</sup> brand of ‘methotrexate, injection 7.5 mg in 0.15 mL pre-filled syringe, injection’;
- the Trexject<sup>®</sup> brand of ‘methotrexate, injection 10 mg in 0.2 mL pre-filled syringe, injection’;
- the Trexject<sup>®</sup> brand of ‘methotrexate, injection 15 mg in 0.3 mL pre-filled syringe, injection’;
- the Trexject<sup>®</sup> brand of ‘methotrexate, injection 20 mg in 0.4 mL pre-filled syringe, injection’;
- the Trexject<sup>®</sup> brand of ‘methotrexate, injection 25 mg in 0.5 mL pre-filled syringe, injection’ and;
- the Claris Lifesciences Zoledronic Acid<sup>®</sup> brand of ‘zoledronic acid, injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL vial, injection’.

#### *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 containing granisetron for administration by injection.

Further, it affects companies that are Responsible Persons for brands of the following pharmaceutical items:

- methotrexate, injection 7.5 mg in 0.15 mL pre-filled syringe, injection;
- methotrexate, injection 10 mg in 0.2 mL pre-filled syringe, injection;
- methotrexate, injection 15 mg in 0.3 mL pre-filled syringe, injection;
- methotrexate, injection 20 mg in 0.4 mL pre-filled syringe, injection;
- methotrexate, injection 25 mg in 0.5 mL pre-filled syringe, injection and;
- zoledronic acid, injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL vial, injection.

All of the affected companies were consulted about the amendments. 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 – October 2018 reduction day)***  
***Amendment Determination 2018***

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 2018 reduction day) Determination 2018* (the Principal Instrument) to:

a) re-allocate brands of pharmaceutical items that no longer meet criteria for a price reduction on reduction day, and b) insert prices for six new brands of six 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.

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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