

EXPLANATORY STATEMENT
INSTRUMENT NUMBER PB 9 OF 2019

NATIONAL HEALTH ACT 1953

***National Health (Weighted average disclosed price – April 2019 reduction day)
Amendment Determination 2019***

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 2019 reduction day) Determination 2018* (PB 109 of 2018) (the Principal Instrument) by:

- inserting a WADP for the first new brands of new pharmaceutical items containing hypromellose for administration by application to the eye (hypromellose).

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 2018 (2019 April cycle).

Amendments

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 30 September 2018 and 31 March 2019 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 two brands of one new pharmaceutical item that are included in this amending instrument, as follows:

- the Genteal[®] brand of ‘hypromellose, eye drops 3 mg per mL, 10 mL, application to the eye’ and;
- the In a Wink Moisturising[®] brand of ‘hypromellose, eye drops 3 mg per mL, 10 mL, application to the eye’.

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 brands of the following pharmaceutical item:

- hypromellose, eye drops 3 mg per mL, 10 mL, application to the eye;

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 – April 2019 reduction day)
Amendment Determination 2019

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 2019 reduction day) Determination 2018* (the Principal Instrument) to: a) allocate two new brands of a new pharmaceutical item that do not meet criteria for a price reduction on reduction day, and b) insert prices for two new brands of one new pharmaceutical item.

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 2019 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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