EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 8 of 2014

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – main disclosure cycle) Amendment Determination 2014 (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 1960* (the Regulations); and
- paragraph 99ADH(1)(aa) of the Act which provides for the Minister to determine, by legislative instrument, a reduction day in relation to a brand of pharmaceutical item.

Purpose

This legislative instrument revokes the determination of a WADP for all brands of pharmaceutical items containing the drug morphine for administration by injection (*morphine injection*) made in the *National Health (Weighted average disclosed price – main disclosure cycle) Determination 2013 (No. 2)* (PB 82 of 2013) (the Principal Instrument). The Principal Instrument was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act for brands in the main price disclosure cycle with a data collection period ending 30 September 2013 (2014 main cycle).

As a result of the amending instrument no price disclosure reduction would apply to brands of morphine injection on 1 April 2014.

The calculation for a WADP compares the sale price disclosed by a responsible pharmaceutical company for a brand of pharmaceutical item against the approved ex-manufacturer price (AEMP) of the pharmaceutical item on the relevant day. Even though the morphine injection brands were sold against a lower price in place for much of the data collection period, in accordance with the Regulations the disclosed price was compared to the higher increased price in place on the 'relevant day' (30 September 2013). This gave the appearance of discounting, resulting in a significant weighted average percentage difference (WAPD) between the sale price and the approved price, when it appears that the manufacturer was actually selling at or close to the AEMP across the drug and manner of administration both prior to and after the price increase.

Morphine injection brands had an unadjusted price reduction of more than 10% and were therefore in Schedule 1 of the Principal Instrument (i.e. taking a reduction). If there had not been a price increase during the data collection period, the unadjusted

price reductions would have certainly been less than 10% and brands containing morphine injection would not have taken price disclosure reductions.

It is considered appropriate to revoke the WADP determinations for brands containing morphine injection, removing the requirement for a price disclosure reduction with expected increases in price shortly thereafter.

In the case of morphine injection: a) the company has asked that the price increase that took effect during the data collection period be maintained; b) all brands across the drug and manner of administration are impacted and have the same responsible person; c) there is a high clinical need for the medicine; d) there has been no or insignificant discounting across the drug/MoA even after the price increases; and e) the medicine recently experienced a critical supply shortage.

None of the small number of other medicines that had a price increase during the data collection period and are subject to a 1 April 2014 price disclosure reduction fit these criteria.

Revocation

This instrument revokes previous determinations made under subsection 99ADB(4)and paragraph 99ADH(1)(aa) of the Act for all brands containing morphine injection in the 2014 main cycle (PB 82 of 2013).

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke the determinations made under subsection 99ADB(4)and paragraph 99ADH(1)(aa) of the Act for morphine injection brands in PB 82 of 2013.

Consultation

This instrument affects the company that is the responsible person for all brands of morphine injection.

The Department discussed this approach with the affected company before making the determination and no concerns were raised.

This instrument commences on the day after it is registered on the Federal Register of Legislative Instruments.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

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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 – main disclosure cycle) Determination 2013 (No. 2)* (the Principal Instrument) by revoking the weighted average disclosed price determinations for all brands of pharmaceutical items containing the drug morphine for administration by injection (*morphine injection*) in the 2014 main cycle with a data collection period ending 30 September 2013. As a result of the determination in the Principal Instrument, a price reduction was scheduled for 1 April 2014 for all brands of morphine injection.

Part VII of the *National Health Act 1953* (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 PBS '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 1960* (the Regulations).

However, this amending instrument revokes the WADP for all brands of morphine injection because the mathematical outcome requiring a reduction only occurred as a result of price increases given to these medicines during the period its data was collected for the 2014 main cycle, and other criteria were met. The instrument will ensure this medicine for which there is a high clinical need is not subject to a price disclosure reduction on 1 April 2014.

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. However, maintenance of the prices for these medicines will support continued patient access to morphine for administration by injection without the need for a reduction followed shortly by a re-increase in price.

Conclusion

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

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