EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 67 OF 2014

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – October 2014 reduction day) 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).

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 2014 reduction day) Determination 2014* (PB 42 of 2014) (the Principal Instrument) by amending the WADP and the AAEMP for all brands of pharmaceutical items containing the drug filgrastim for administration by injection (*filgrastim 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 31 March 2014 (2014 October cycle).

Amendment

The amendment is made following consideration of matters raised by a responsible person for a brand of pharmaceutical item containing filgrastim for injection concerning the WADPs and AAEMPs determined in the Principal Instrument for brands containing filgrastim injection. A review of the determination, in response to the matters raised by the responsible person, resulted in the submission of corrected data by some responsible persons for filgrastim injection brands for the 2014 October cycle.

Schedule 1 of the Principal Instrument includes a WADP and AAEMP for brands of the filgrastim injection pharmaceutical items. This amending instrument inserts the revised WADPs in the appropriate column, and the same amount is also determined as the AAEMP for the brands due to the operation of section 6 of the Principal instrument. These revised figures were worked out under the Act and Regulations based on the corrected disclosed data.

The filgrastim injection listed brands are included in Schedule 1 of the Principal Instrument because they have an unadjusted price reduction that has been calculated to be at least 10%. A responsible person for a listed brand appearing in Schedule 1 of the Principal Instrument will receive a price disclosure reduction on and from 1 October 2014, provided that, on that date, the 'approved ex-manufacturer price' for the listed brand is more than the determined 'AAEMP' for that brand.

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary the determination made under subsection 99ADB(4) for filgrastim injection brands in PB 42 of 2014.

Consultation

This instrument affects companies that are a responsible person for brands of pharmaceutical items containing filgrastim injection. This amending instrument is made as a result of consultation with those affected companies concerning the WADP and AAEMP determinations in the Principal Instrument for brands of filgrastim injection for the 2014 October cycle.

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

National Health (Weighted average disclosed price – October 2014 reduction day) Amendment Determination 2014 (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 – October 2014 reduction day) Determination 2014* (the Principal Instrument) by amending the weighted average disclosed price determination for all brands of pharmaceutical items containing the drug filgrastim for administration by injection (*filgrastim injection*) in the 2014 October cycle with a data collection period ending 31 March 2014 (2014 October cycle). As a result of the determination in the Principal Instrument, a price disclosure reduction was scheduled for 1 October 2014 for all brands of filgrastim 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 '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).

The amendment is made based on corrected data received from some companies after consideration of matters raised by a responsible person concerning the WADPs and AAEMPs determined in the Principal Instrument for filgrastim injection brands.

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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