EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 37 of 2013

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – main disclosure cycle) Amendment Determination 2013 (No. 2)

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 – main disclosure cycle) Determination 2013(No. 1)* (PB 26 of 2013) (the Principal Instrument), which is made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act and makes certain determinations relating to price disclosure for listed brands in the main disclosure cycle with a data collection period ending 30 September 2012.

The purpose of this amending instrument is to amend the WADP and the AAEMP for two brands of pharmaceutical items that were incorrect in the Principal Instrument because an out of date quantity was used for one brand of pharmaceutical item with the drug etoposide administered by injection when working out the WADP for all brands with that drug and manner of administration. The new WADP for the Etoposide Ebewe brand is made for the corrected quantity. The very small adjustment to the WADP for the Etopophos brand was caused by the correction to the quantity used for the other brand.

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 August 2013, provided that, on that date, the 'approved ex-manufacturer price' for the listed brand is more than the determined 'AAEMP' for that brand.

Schedule 1 of the Principal Instrument includes a WADP and AAEMP for the two affected brands of 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. These 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%.

Consultation
This instrument affects two pharmaceutical companies that are responsible persons for brands of two pharmaceutical items containing the drug etoposide administered by injection, which are due for price disclosure reduction on 1 August 2013.

The Department wrote to the two affected companies on 28 May 2013, and telephoned the companies to discuss the issue. Neither company indicated concern about the change to the WADP and AAEMP which flowed from correction to the quantity used in calculations for one of the medicines.

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 – main disclosure cycle) Amendment Determination 2013 (No. 2)

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. 1)* (the Principal Instrument) by amending a determination relating to price disclosure for two brands of pharmaceutical item in the second main disclosure cycle with a data collection period ending 30 September 2012.

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).

This amending instrument inserts into the Principal Instrument a revised weighted average disclosed price (WADP) for two brands of pharmaceutical item that were incorrect in the Principal Instrument because the WADP was calculated for an out of date quantity of the relevant medicine. The reduction day remains 1 August 2013.

A responsible person for a listed brand in Schedule 1 of this instrument, provided that the 'approved ex-manufacturer price' for the listed brand on 1 August 2013 is more than the 'adjusted approved ex-manufacturer price', will receive a price reduction for the listed brand on and from 1 August 2013: subsections 99ADH(3) and (4).

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. Price disclosure 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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