EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 38 of 2013

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – supplementary disclosure cycle A) Amendment Determination 2013 (No. 1)

Authority

This legislative instrument is made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the *National Health Act 1953* (the Act), which provide 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 that the Minister may determine a reduction day for a listed brand with a WADP determined.

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 – supplementary disclosure cycle A) Determination 2013 (PB 24 of 2013)* (the Principal Instrument), which was made pursuant to subsection 99ADB(4) and paragraph 99ADH(1)(aa) of the Act and makes certain determinations relating to price disclosure for a listed brand in the supplementary disclosure cycle A with a data collection period ending 31 January 2013.

The purpose of this amending instrument is to add a listed brand of a new pharmaceutical item that was listed on the Pharmaceutical Benefits Scheme (PBS) after the Principal Instrument was made, but prior to the reduction day of 1 August 2013, and which has been allocated to the supplementary disclosure cycle A by regulation 37F of the Regulations (new listed brand of new pharmaceutical item). The same reduction day is determined for the listed brand in this Instrument as for listed brands in the Principal Instrument (1 August 2013).

New listed brands of existing pharmaceutical items that listed on the PBS after the Principal Instrument was made but prior to the reduction day are not included in this amending instrument as they will receive a flow-on reduction under section 99ADHA of the Act on 1 August 2013 if at least one existing brand of the same pharmaceutical item is in Schedule 1of the principal instrument.

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.

New listed brands
The new listed brand of new pharmaceutical item containing *orally administered temozolomide* that is added to PB 24 of 2013 by this instrument was listed on the PBS on 1 May 2013. The new pharmaceutical item is the 180mg capsule of orally administered temozolomide.

The new entry for the brand containing the drug temozolomide is inserted into Schedule 1 of the Principal Instrument because the listed brand has an unadjusted price reduction that has been calculated to be at least 10%.

A further new brand of the 180mg capsule of orally administered temozolomide pharmaceutical item was listed on 1 June 2013. It will receive the flow-on reduction under section 99ADHA of the Act on 1 August 2013.

Consultation

This instrument affects pharmaceutical companies with medicines containing the orally administered 180mg capsule form of the drug temozolomide listed on the PBS. It is machinery in nature and does not substantially alter existing arrangements. The instrument is required to apply the 1 August 2013 price disclosure reduction for PBS listed medicines containing orally administered temozolomide to newly listed brands of a new pharmaceutical item containing orally administered temozolomide. The price disclosure reduction for orally administered temozolomide was notified to all pharmaceutical companies with PBS listed medicines by email on 26 April 2013 and also on the pbs.gov.au website.

Further, the current provisions under the Act that apply the orally administered temozolomide price disclosure reduction to brands of newly listed pharmaceutical items came into effect on October 2012. Pharmaceutical companies were consulted prior to the introduction of the amendments in early 2012 through meetings with peak body organisations. The peak bodies consulted included Medicines Australia, the Generic Medicines Industry Association of Australia, The Pharmacy Guild of Australia, the National Pharmaceutical Services Association, Australian Pharmaceutical Industries, and Consumers Health Forum. Educational and information meetings were also conducted for individual companies prior to the October 2012 commencement of the relevant provisions in the Act.

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 – supplementary disclosure cycle A) Amendment Determination 2013 (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 – supplementary disclosure cycle A) Determination 2013* (PB 24 of 2013) (the Principal Instrument) by making certain determinations relating to price disclosure for a brand of pharmaceutical item in the supplementary disclosure cycle A with a data collection period ending 31 January 2013.

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 Weighted Average Disclosed Price for a new brand of new pharmaceutical item listed after the end of the data collection period and prior to the reduction day. The reduction day for the new listed brand is 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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