

EXPLANATORY STATEMENT
INSTRUMENT NUMBER PB 70 of 2012

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – interim supplementary disclosure cycle) Amendment Determination 2012

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) and the adjusted approved price to pharmacists (AAPTP) for the listed brand.

Purpose

This legislative instrument amends the *National Health (Weighted average disclosed price – interim supplementary disclosure cycle) Determination 2012* (PB 58 of 2012) (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 interim supplementary disclosure cycle with a data collection period ending 31 May 2012.

The purpose of this amending instrument is to add listed brands that were listed on the Pharmaceutical Benefits Scheme (PBS) after the Principal Instrument was made, but prior to the reduction day of 1 December 2012, and which have been allocated to the interim supplementary disclosure cycle by regulation 37F of the Regulations (new listed brands). Brands which are no longer listed on the PBS are also removed.

Only 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 December 2012, provided that, on that date, the ‘approved ex-manufacturer price’ for the listed brand is more than the determined ‘AAEMP’ for that brand.

Item 77(3) of Schedule 1 of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*, which amends the Act commencing 1 October 2012, will provide that if a WADP and reduction day has been determined for a listed brand before 1 October 2012 and the reduction day is after 1 October 2012 then for the purposes of applying a price reduction under section 99ADH of the Act on the reduction day to the listed brand the adjusted approved ex-manufacturer price is deemed to be the same as the WADP for that listed brand. Due to this transitional

provision the WADP rather than the adjusted approved price to pharmacists will be used for the purposes of price reductions on the reduction day.

New listed brands

The new listed brands listed on the PBS on 1 September 2012.

Each entry for a new listed brand is inserted into Schedule 1 of the Principal Instrument because these listed brands have an unadjusted price reduction that has been calculated to be at least 10%.

Consultation

This instrument affects pharmaceutical companies with medicines listed on the PBS. Pharmaceutical companies have been consulted in relation to the introduction of price disclosure requirements during both the policy development and implementation of the further PBS reforms of 2010. This has occurred through meetings with both peak body organisations and individual companies. Information on the price disclosure measure has been disseminated through peak industry bodies, during regular meetings with the Price Disclosure Working Group and direct to responsible persons through information sessions and educational workshops.

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 – interim supplementary disclosure cycle) Amendment Determination 2012

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

The purpose of this amending instrument is to add listed brands that were listed on the Pharmaceutical Benefits Scheme (PBS) after the Principal Instrument was made but prior to the reduction day of 1 December 2012, and which have been allocated to the interim supplementary disclosure cycle by regulation 37F of the Regulations (new listed 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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