EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 12 OF 2017

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2017 reduction day) Amendment Determination 2017 (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 – April 2017 reduction day) Determination 2016* (PB 109 of 2016) (the Principal Instrument) by amending the WADP determinations for all brands of pharmaceutical items containing the drugs iron polymaltose complex by injection (iron polymaltose complex), sorbitol with sodium citrate and sodium lauryl sulfoacetate for rectal administration (sorbitol with sodium citrate and sodium lauryl sulfoacetate), ursodeoxycholic acid for oral administration (ursodeoxycholic acid), and zoledronic acid by injection (zoledronic acid).

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 30 September 2016 (2017 April cycle).

Amendments

Amendments are being made following consideration of matters raised by responsible persons concerning the determinations in the Principal Instrument for brands of pharmaceutical items containing iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, ursodeoxycholic acid and zoledronic acid. A review of determinations in response to matters raised by responsible persons revealed that incorrect data had been submitted by some responsible persons. Corrected data was submitted by some responsible persons for certain brands containing the drugs set out above. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations.

This amending instrument removes the previous WADPs for brands of iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, ursodeoxycholic acid and zoledronic acid. Revised WADPs for brands of zoledronic acid are inserted in the appropriate column in Schedule 1 and revised WADPs for brands of iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, and ursodeoxycholic acid are inserted in Schedule 2.

Listed brands of zoledronic acid are included in Schedule 1 of the Principal Instrument because they continue to have an unadjusted price reduction of at least 10 per cent. Listed brands of iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, and ursodeoxycholic acid are inserted in Schedule 2 of the Principal Instrument because their unadjusted price reduction following determination of the amended WADP is less than 10%.

Basis for amendments

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to vary or revoke the determination made under subsection 99ADB(4) for the medicines affected by this amending instrument.

Consultation

This instrument affects companies that are a responsible person for brands of pharmaceutical items containing iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, ursodeoxycholic acid, and zoledronic acid.

Each of the affected companies were consulted about the amendments. No concerns were expressed.

This instrument commences on the day after it is registered on the Federal Register of Legislation. This instrument is a legislative instrument for the purposes of the *Legislation 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 – April 2017 reduction day) Determination 2016* (the Principal Instrument) to adjust the weighted average disclosed prices of brands of iron polymaltose complex, sorbitol with sodium citrate and sodium lauryl sulfoacetate, ursodeoxycholic acid and zoledronic acid calculated using corrected data provided by companies.

Part VII of 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 Regulations.

The amendments are made to provide for correct and effective reductions in prices for pharmaceutical benefits on 1 April 2017 under the statutory provisions for price disclosure.

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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