EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 12 OF 2021

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2021 reduction day) Amendment Determination 2021

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 2017* (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 2021 reduction day) Determination 2020* (PB 123 of 2020) (the Principal Instrument) by:

- amending the WADPs for brands of the pharmaceutical item:
  - nortriptyline, tablet 10 mg (as hydrochloride), oral;
  - nortriptyline, tablet 25 mg (as hydrochloride), oral;
  - trastuzumab, powder for I.V. infusion 420 mg, injection;
  - trasutzumab, powder for I.V. infusion 60 mg, injection; and
  - trastuzumab, powder for I.V. infusion 150 mg, injection.
- removing from Schedule 1 and inserting in Schedule 2 WADPs for brands of pharmaceutical items containing:
  - rituximab, solution for subcutaneous injection containing rituximab 1400 mg in 11.7 mL, injection;
  - teriflunomide, tablet 14 mg, oral;
  - voriconazole, tablet 200 mg, oral; and
  - voriconazole, tablet 50 mg, oral.
- inserting WADPs for brands of new pharmaceutical items that listed after publication of the Principle Instrument:
  - fluoxetine, capsule 20 mg as hydrochloride USP, oral;
  - norethisterone with ethinylestradiol, pack containing 21 tablets 1 mg 35 micrograms and 7 inert tablets USP, oral;
  - pindolol, tablet 5 mg USP, oral;
  - sertraline, oral;
    - tablet 50mg (as hydrochloride) USP;
    - tablet 100mg (as hydrochloride) USP; and
  - topotecan, solution concentrate for I.V. infusion 4 mg in 4 mL as hydrochloride, 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 30 September 2020 (2021 April cycle).

Amendments

Revision of WADP determinations for Brands of Pharmaceutical Items

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 nortriptyline, rituximab, teriflunomide, trastuzumab, and voriconazole.

A review of determinations in response to matters raised by Responsible Persons revealed that:

- A Responsible Person for a brand of teriflunomide had submitted incorrect data. Corrected data was resubmitted. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations, moving this drug from Schedule 1 to Schedule 2;
- Responsible Persons for brands of nortriptyline and trastuzumab had submitted incorrect data. Corrected data was resubmitted. New calculations for the WADPs set out in this amending determination in Schedule 1 were completed in accordance with the Act and Regulations;
- The subcutaneous form of rituximab will not take a scheduled reduction due to the outcome of a dispute focusing on its commercial viability and patient access; and
- Voriconazole will not take a scheduled reduction due to the correct threshold for its calculations being 30 per cent, moving the drug from Schedule 1 to Schedule 2.

Insertion of WADP determinations for New Brands of New Pharmaceutical Items

WADPs need to be determined for new pharmaceutical items that listed on the F2 formulary between 30 September 2020 and 1 April 2021. Examples are s19A temporary listings (fluoxetine, pindolol, sertraline and norethisterone with ethinylestradiol) and new forms or pack sizes of drugs (topotecan).

There are six new pharmaceutical items that are included in this amending instrument, as follows:

- fluoxetine, capsule 20 mg as hydrochloride USP, oral;
- norethisterone with ethinylestradiol, pack containing 21 tablets 1 mg 35 micrograms and 7 inert tablets USP, oral;
- pindolol, tablet 5 mg USP, oral;
- sertraline, oral;
    - tablet 50mg (as hydrochloride) USP;
    - tablet 100mg (as hydrochloride) USP; and
- topotecan, solution concentrate for I.V. infusion 4 mg in 4 mL as hydrochloride, injection.

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 Responsible Persons for all brands of all pharmaceutical items containing nortriptyline, rituximab, teriflunomide, trastuzumab, and voriconazole.

All of the affected Responsible Persons were consulted about the amendments. No additional consultation with experts was undertaken, as consultation with affected Responsible Persons drew on the knowledge of persons with relevant expertise.

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 2021 reduction day) Determination 2020* (the Principal Instrument) to: a) amend prices of brands of pharmaceutical items which continue to have a price reduction on reduction day, b) remove brands of pharmaceutical items which will no longer have a price reduction on reduction day, and c) insert prices for new brands of new pharmaceutical items.

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 2021 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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