EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 13 OF 2020

NATIONAL HEALTH ACT 1953

National Health (Weighted average disclosed price – April 2020 reduction day) Amendment Determination 2020

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 2020 reduction day) Determination 2019* (PB 103 of 2019) (the Principal Instrument) by:

- amending the WADPs for brands of pharmaceutical items containing:
    - abacavir with lamivudine for oral administration (abacavir with lamivudine);
    - ezetimibe for oral administration (ezetimibe); and
    - olmesartan for oral administration (olmesartan); and
    - tobramycin for administration by inhalation (tobramycin inhalation);
- removing from Schedule 1 WADPs and inserting in Schedule 2 for brands of pharmaceutical items containing:
    - ezetimibe with simvastatin for oral administration (ezetimibe with simvastatin);
    - olmesartan with hydrochlorothiazide for oral administration (olmesartan with hydrochlorothiazide);
    - pegfilgrastim for administration by injection (pegfilgrastim);
    - rasagiline for oral administration (rasgiline); and
    - tobramycin for administration of inhalation by mouth (tobramycin inhalation by mouth).
- inserting WADPs for the first new brand of new pharmaceutical items containing:
    - isotretinoin for oral administration (isotretinoin);
    - levodopa with carbidopa for oral administration (levodopa with carbidopa); and
    - tacrolimus for oral administration (tacrolimus).

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 2019 (2020 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 abacavir with lamivudine, ezetimibe, ezetimibe with simvastatin, olmesartan, olmesartan with hydrochlorothiazide, pegfilgrastim, rasgiline, rosuvastatin and tobramycin.

A review of determinations in response to matters raised by responsible persons revealed that incorrect data had been submitted by some responsible persons for all of the drugs cited above. Corrected data was submitted. New calculations for the WADPs set out in this amending determination were completed in accordance with the Act and Regulations.

Insertion of WADP determinations for New Brands of New Pharmaceutical Items

A WADP is required to be determined for new brands of pharmaceutical items listing between 30 September 2019 and 31 March 2020 that have no other existing brand of the same pharmaceutical item (including a single brand pharmaceutical item where the brand or pharmaceutical item changes, or where all existing brands change).

There are three brands of three new pharmaceutical items that are included in this amending instrument, as follows:

- the ADVAGRAF XL® brand of 'tacrolimus, capsule 3 mg (once daily prolonged release)';
- the Oratane® brand of 'isotretinoin, capsule 30 mg, oral'; and
- the Sinemet CR Prolonged-Release Tablets® brand of 'levodopa with carbidopa, tablet (prolonged release) 200 mg-50 mg'.

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 abacavir with lamivudine, ezetimibe, ezetimibe with simvastatin, olmesartan, olmesartan with hydrochlorothiazide, pegfilgrastim, rasgiline, and tobramycin.

This instrument also affects the responsible persons for ADVAGRAF XL, Oratane, and Sinemet CR Prolonged-Release Tablets.

All of the affected responsible persons were consulted about the amendments. While some responsible persons requested clarification of the impact of this instrument, all concerns raised have been addressed.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

National Health (Weighted average disclosed price – April 2020 reduction day) Amendment Determination 2020

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 2020 reduction day) Determination 2019* (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 2020 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.

Adriana Platona
First Assistant Secretary
Technology Assessment and Access Division
Department of Health