EXPLANATORY STATEMENT

National Health Act 1953

National Health (Price and Special Patient Contribution) Determination 2021

PB 35 of 2021

Authority

This legislative instrument is made pursuant to subsections 85B(2), (3) and (4) of *National Health Act 1953* (the Act).

Purpose

The purpose of the *National Health (Price and Special Patient Contribution) Determination 2021* (the Determination) is to determine prices and claimed prices by reference to the pricing and pack quantity of the listed brand of pharmaceutical item, and the circumstances in which the Commonwealth is to pay the special patient contribution for the brand of pharmaceutical item. The Determination repeals and replaces the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010) (sunsetting Determination), which sunsets on 1 April 2021.

The Act provides for the Minister and the responsible person to agree to a price that is taken to be the appropriate maximum price of a brand of a pharmaceutical item for the purposes of Part VII of the Act (section 85AD). Section 85B of the Act applies if the Minister and the responsible person have been unable to reach an agreement on a price for the *pricing quantity*. Whether or not an agreement is made for the *pricing quantity*, section 85B also applies if the responsible person is dissatisfied with the *proportional ex-manufacturer prices* that will apply to other *pack quantities*.

Subsection 85B(2) provides that the Minister may determine, by legislative instrument and by reference to the *pricing quantity* of a brand of a pharmaceutical item, an amount that is taken to be the appropriate maximum price of the brand for the purposes of Part VII of the Act. This is termed the 'Determined Price' in this Determination.

Subsection 85B(3) provides that the Minister may determine, by legislative instrument and by reference to a *pack quantity* of a brand of the pharmaceutical item, an amount that is taken to be the price claimed by the responsible person for the *pack quantity* of the brand, for the purposes of Part VII of the Act. This is termed the 'Claimed Price' in this Determination.

The Determined Price is the *approved ex-manufacturer price* and is used as the basis for working out the Commonwealth price for the brand of the pharmaceutical item (section 98B of the Act); for *pack quantities* other than the *pricing quantity*, the *proportional ex-manufacturer price* is used as the basis. Approved pharmacists are entitled to payment from the Commonwealth equal to the Commonwealth price less the applicable patient co-payment (section 99 of the Act).

The difference between the responsible person's Commonwealth price for a *pack quantity* (i.e. the price that would be the Commonwealth price if the responsible person's claimed price had become the *approved ex-manufacturer price* or the *proportional ex-manufacturer price* for that *pack quantity*) and the Commonwealth price for the *pack quantity* is defined in

subsection 85B(5) of the Act as the *special patient contribution*. An approved pharmacist may charge a patient an amount equal to the special patient contribution, in addition to any other amount that may be charged (subsection 87(2A) of the Act).

Subsection 85B(4) of the Act provides that the Minister may determine the circumstances in which the Commonwealth is to pay the special patient contribution for a brand of a pharmaceutical item. In such cases, the Commonwealth payment to the pharmacist is increased by the amount of the special patient contribution (subsection 99(2AA) of the Act) and the pharmacist may not charge the patient this amount (subsection 87(2A) of the Act).

The purpose of making subsection 85B(4) determinations is to enable patients for whom the base-priced brands (the ones without a special patient contribution) are not suitable, to obtain the higher priced brand (the one with the special patient contribution) without the need to pay the higher price. In such cases the Commonwealth pays the special patient contribution.

An example of how this operates is as follows. There are three brands of the pharmaceutical item which is made up of the drug apple, the form 100 mg sphere and the manner of administration oral. The three brands are Rosy Red, Red Apple and Apple 100 mg. All three brands of the pharmaceutical item have a pricing quantity of 30. The Determined Price for all three brands is $5.00.

The Minister and the responsible person for the brand Rosy Red were not able to agree on the Determined Price for Rosy Red, so the responsible person requested that the Minister determine a Claimed Price for Rosy Red. The Minister determines a claimed price of $6.00 for Rosy Red.

If a patient chooses to access the Rosy Red brand of apple, 100 mg sphere, oral, the patient pays a special patient contribution. The special patient contribution is calculated as the difference between the Commonwealth price for Red Apple and Apple 100 mg (which is the same for both brands) and the Commonwealth price for Rosy Red (which is higher). The Minister may determine that if particular circumstances are met, the Commonwealth will pay the special patient contribution for Rosy Red.

Subsection 85B(4) provides that the Commonwealth may pay the special patient contribution for a brand of a pharmaceutical item if the following conditions apply:

- the brand is mentioned in Schedule 2 of the Determination; and
- the circumstances detailed in Schedule 2 for the specified drug are met; and
- the circumstance in which the brand is prescribed is a circumstance determined under paragraph 85(7)(b) of the Act; and
- the prescription is written in compliance with authority required procedures for authorisation by the Chief Executive Medicare, explained in sections 11, 12 and 13 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)*.

Consultation
The Determination affects certain responsible persons with brands of pharmaceutical items listed on the PBS.

Before a brand of a drug is listed on the PBS, and from time to time thereafter, price negotiations occur between the responsible person and the Minister for the purpose of reaching a price agreement for section 85AD of the Act. If the Minister and the responsible person do not agree on a price, further consultation occurs with the responsible person, and thereafter the Minister determines the price that will be the approved ex-manufacturer price for the brand. The Minister also determines the corresponding price claimed by the responsible person, which is used to calculate the special patient contribution that will apply to the brand.

The majority of items listed in the Determination were listed in the sunsetting Determination which sunsets on 1 April 2021. Responsible persons were consulted about changes to their items as they occurred from time to time.

The Determination differs from the sunsetting Determination, by changing determined and claimed prices for the following items that have been subject to price disclosure reductions to the determined and claimed prices under subsections 99ADB(4) and 99ADH(4) of the Act:

- ezetimibe, tablet 10 mg, Ezetrol;
- ezetimibe with rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium), Rosuzet Composite Pack;
- ezetimibe with rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium), Rosuzet Composite Pack;
- ezetimibe with rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium), Rosuzet Composite Pack;
- ezetimibe with rosuvastatin, pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium), Rosuzet Composite Pack;
- ibuprofen, tablet 400 mg, Brufen;
- olmesartan with amlodipine, tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate), Sevikar 40/5;
- olmesartan with amlodipine, tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate), Sevikar 40/10;
- olmesartan with amlodipine and hydrochlorothiazide, tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 20/5/12.5;
- olmesartan with amlodipine and hydrochlorothiazide, tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 40/5/12.5;
- olmesartan with amlodipine and hydrochlorothiazide, tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/5/25;
- olmesartan with amlodipine and hydrochlorothiazide, tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 40/10/12.5;

- olmesartan with amlodipine and hydrochlorothiazide, tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/10/25;
- rosuvastatin, tablet 5 mg (as calcium), Crestor;
- rosuvastatin, tablet 20 mg (as calcium), Crestor; and
- rosuvastatin, tablet 40 mg (as calcium), Crestor.

The Determination affects responsible persons for brands of these pharmaceutical items. All of the affected responsible persons were consulted about the price reductions and given an opportunity to raise any objections. No objections were raised by affected responsible persons for these brands of pharmaceutical items. No additional consultation with experts was undertaken, as consultation with affected responsible persons drew on the knowledge of persons with relevant expertise.

Captopril, tablet 25 mg, Zedace and captopril, tablet 50 mg, Zedace are not included in the Determination as the responsible person requested deletion of these brands from the PBS from 1 April 2021.

A determined and claimed price for salbutamol, pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation), Asmol CFC-Free with dose counter is included in the Determination, after the responsible person made a submission requesting that the Minister determine a claimed price for those brands. The responsible person was advised of the delegate's intention to determine in accordance with its request.

Administrative corrections were made to three items and included the following:

- Removal of allopurinol tablet 100 mg quantity 100;
- Addition of determined price to allopurinol tablet 200 mg quantity 200;
- Amend form description for clonazepam from "tablet 500 mcg" to "tablet 500 micrograms"; and
- Amend the pricing and pack quantity of salbutamol nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20 from "20" to "1".

No additional consultation with experts was undertaken regarding the Determination because consultation with the affected responsible persons drew on the knowledge of persons with relevant expertise.

A provision-by-provision description of the Determination is contained in the Attachment.

The Determination commences on 1 April 2021.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT

DETAILS OF THE *NATIONAL HEALTH (LISTED DRUGS OF F1 OR F2) DETERMINATION 2021*

Section 1 Name
This section provides that the name of the Determination is the *National Health (Price and Special Patient Contribution) Determination 2021*
This section also provides that the instrument may be cited as PB 35 of 2021.

Section 2 Commencement
This section provides that the Determination commences on 1 April 2021.

Section 3 Authority
This section provides that the Determination is made under section 85B of the *National Health Act 1953*.

Section 4 Schedule 3
This section provides that the sunsetting Determination is repealed.

Section 5 Definitions
This section provides definitions of:

> ***Act*** meaning the *National Health Act 1953*.
>
> ***base- priced drug*** meaning all brands of pharmaceutical items or brands of drugs in the same therapeutic group, that are not subject to a claimed price.
>
> ***pack quantity*** meaning the quantity or number of units the Minister has determined by legislative instrument for the brand of a pharmaceutical item (in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012 (PB 71 of 2012)*).
>
> ***pricing quantity*** meaning the lowest of any pack quantity of any listed brand of the pharmaceutical item.
>
> ***special patient contribution*** has the meaning given by subsection 85B(5) of the Act.

Section 6 Determined price
This section provides for the amount that is the maximum price for the pricing quantity of all brands of a pharmaceutical item that are not subject to a claimed price. It is the amount mentioned in the column headed 'Determined Price' in Schedule 1.

Section 7 Claimed price
This section provides for the amount that is the maximum price for the pricing quantity for the brand of the pharmaceutical item. It is the amount mentioned in the column headed 'Claimed Price' in Schedule 1, for the brand mentioned in the column headed 'Brand' in Schedule 1.

Section 8 Commonwealth payment of special patient contribution

This section provides that the circumstances in which the Commonwealth will pay the special patient contribution are set out in Schedule 2.

Schedule 1 Determined and claimed prices

This schedule lists brands of pharmaceutical items for which the Minister has determined prices and claimed prices by reference to the pack quantity.

Schedule 2 Pharmaceutical benefits for which the Commonwealth will pay the special patient contribution

This schedule lists brands of pharmaceutical items and the circumstances for which the Commonwealth is to pay the special patient contribution.

Schedule 3 Repeals

This schedule repeals the sunsetting Determination.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Price and Special Patient Contribution) Determination 2021 (PB 35 of 2021)

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 Legislative Instrument is made pursuant to subsection 85B of the *National Health Act 1953* (the Act), which provides for price determinations in relation to brands of pharmaceutical items listed on the Pharmaceutical Benefits Scheme (PBS), for which the Minister and the responsible person have not been able to make a price agreement. It also provides for the circumstances in which the Commonwealth will pay the special patient contribution resulting from these price determinations.

Human rights implications

The Determination engages Article 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 benefits scheme which assists with providing subsidised access to medicines for people. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Determining prices under section 85B of the Act promotes the efficient operation of the PBS by offering an additional avenue for sponsors to appeal the viability of approved ex-manufacturer prices of pharmaceutical items. Government policy includes that prices may only be determined under section 85B of the Act if at least one brand is available to consumers in sufficient quantities at the benchmark price.

Conclusion

The Legislative Instrument is compatible with human rights, as it promotes the protection of human rights.

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