EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2021 (No. 1)

PB 3 of 2021

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the *National Health Act 1953* (the Act), is to amend the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply.

The *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (the Principal Instrument) expands the list of pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and provides the conditions for such a supply (a 'Continued Dispensing' supply).

The amendments made by this instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply ('Continued Dispensing').

This instrument does not override state and territory poisons laws. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to the eligible medicines.

Amendments made by this Instrument

Schedule 1 to this instrument provides for the addition of forms of the listed drugs fluoxetine, phenelzine, terbutaline, and trihexyphenidyl, and the deletion of a form of the listed drug ocriplasmin to and from the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply. These changes are summarised, by subject matter, in the Attachment.

Consultation

This instrument affects approved pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit. Consultation was undertaken prior to commencement of the Principal Instrument with relevant peak bodies including the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia. The Department has also undertaken direct consultation with Services Australia and has consulted with state and territory Departments of Health about implementation.

It was considered that further consultation for this instrument was unnecessary due to the nature of the consultation that had already taken place.

General

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

This instrument commences on 1 February 2021.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2021 (No. 1)*

1 Name

This section provides that the instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 1)* and may also be cited as PB 3 of 2021.

2 Commencement

This section provides that the instrument commences on 1 February 2021.

3 Authority

This section states that this instrument is made under subsection 89A(3) of the *National Health Act 1953*.

4 Amendments to the *National Health (Continued Dispensing – Emergency Measures) Determination 2020*

The amendments in Schedule 1 involve the addition and deletion of forms of listed drugs to and from the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. These changes are summarised below.

SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) DETERMINATION 2020* MADE BY THIS INSTRUMENT

Forms Added

Listed Drug	*Form*
Fluoxetine	Capsule 20 mg (as hydrochloride) (USP)
Phenelzine	Tablet 15 mg (as sulfate) (USP)
Terbutaline	Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 120 doses
Trihexyphenidyl	Tablet containing trihexyphenidyl hydrochloride 2 mg (USP)

Forms Deleted

Listed Drug	*Form*
Ocriplasmin	Solution concentrate for intravitreal injection 0.5 mg in 0.2 mL

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 1)

(PB 3 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

The *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2021 (No. 1)* amends the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* which specifies the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the *National Health Act 1953* without a prescription, and the conditions for such a supply ('Continued Dispensing').

The amendments in Schedule 1 involve the addition and deletion of forms of listed drugs to and from the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply.

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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This legislative instrument is compatible with human rights because it advances the protection of human rights.

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