EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2020 (No. 1)

PB 98 of 2020

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the Act, is to amend the *National Health (Continued Dispensing) Determination 2012* (Principal Determination) to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply, and to update a definition used in the Principal Determination.

The Principal Determination specifies the pharmaceutical benefits that may be supplied, and the conditions that must be satisfied when those pharmaceutical benefits are supplied, by an approved pharmacist without a current prescription, but on the basis of a previous prescription from a PBS prescriber (a Continued Dispensing supply).

The amendments made to Schedule 1 of the Principal Determination by this Instrument provide for the alteration of the names of the listed drugs levonorgestrel with ethinyloestradiol and norethisterone with ethinyloestradiol (removing the 'o' from ethinyloestradiol) and for the deletion of forms of the drugs norethisterone with ethinyloestradiol and fluvastatin from the list of drugs that may be supplied as a Continued Dispensing supply. These changes reflect amendments previously made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012). 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.

This Instrument also provides for amendment of the definition of "PSA Guidelines", in order to update the version of the PSA Guidelines that applies to that which is in force on the day this Instrument takes effect. The PSA Guidelines, which are the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists,* are prepared and issued by the Pharmaceutical Society of Australia. In conducting a Continued Dispensing supply, the Determination requires pharmacists to consider the PSA Guidelines. The PSA Guidelines are incorporated by reference into this instrument (sections 2.01 and 2.10) and are freely available from the Pharmaceutical Society of Australia website at www.psa.org.au/.

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

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').

Consultation

Broad consultation was undertaken throughout the development of the Continued Dispensing supply initiative. A public written consultation process was undertaken in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiative. The Department has continued to engage with stakeholder groups, including the Pharmaceutical Society of Australia, Services Australia and state and territory Health departments, as individual issues are identified.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that has already taken place, and the minor and machinery nature of the amendments being made by this Instrument.

General

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

This instrument commences on 1 October 2020.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (CONTINUED DISPENSING) AMENDMENT DETERMINATION 2020 (No. 1)*

1 Name of Instrument

This section provides that this Instrument is the *National Health (Continued Dispensing) Amendment Determination 2020 (No. 1)* and that it may also be cited as PB 98 of 2020.

2 Commencement

This section provides that the instrument commences on 1 October 2020.

3 Authority

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

4 Amendments to *National Health (Continued Dispensing) Determination 2012*

The amendments in Schedule 1 involve the alteration of the name of two listed drugs and the deletion of three forms of listed drugs from the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. These changes are summarised below. The amendments in Schedule 1 also involve an alteration of the definition of PSA Guidelines, to update the applicable version to that which is in force on the day this Instrument takes effect.

SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (CONTINUED DISPENSING) DETERMINATION 2012* MADE BY THIS INSTRUMENT

Alteration of Listed Drug Name

Listed Drug

From: Levonorgestrel with Ethinyloestradiol
To: Levonorgestrel with ethinylestradiol

From: Norethisterone with Ethinyloestradiol
To: Norethisterone with ethinyloestradiol

Forms Deleted

Listed Drug	***Form***
Norethisterone with Ethinylestradiol	Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets
Fluvastatin	Capsule 20 mg (as sodium)
	Capsule 40 mg (as sodium)

Documents Incorporated by Reference

Document incorporated	*Document access*
Pharmaceutical Society of Australia Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists (PSA Guidelines). The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act* 2003. The PSA Guidelines provides advice to pharmacists on the appropriate and effective processes, desired behaviours of good practice, how to fulfil professional responsibilities, and the expected outcomes for dispensing eligible medicines under the Continued Dispensing supply provisions of the PBS	The PSA Guidelines are freely available from the Pharmaceutical Society of Australia website at www.psa.org.au/

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing) Amendment Determination 2020 (No. 1)

(PB 98 of 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

The *National Health (Continued Dispensing) Amendment Determination 2020 (No. 1)* amends the *National Health (Continued Dispensing) Determination 2012* (Principal Determination) 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 alteration of the name of two listed drugs and the deletion of three forms of listed drugs from the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. They also involve an alteration of the definition of PSA Guidelines, to update the applicable version to that which is in force on the day this Instrument takes effect.

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 for people to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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