

# EXPLANATORY STATEMENT

## *National Health Act 1953*

### ***NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2020 (No. 8)***

#### **PB 91 of 2020**

#### **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.

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). The PSA Guidelines are freely available from the Pharmaceutical Society of Australia website at [www.psa.org.au/](http://www.psa.org.au/).

#### **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 deletion of the listed drugs daclatasvir, danazol and dipyridamole and for the deletion of two forms of the listed drug dexamethasone from the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply. It also provides for the addition of the listed drug apomorphine and for the addition of forms of the listed drugs aflibercept and amino acid formula with vitamins and minerals without phenylalanine to that list. These changes are summarised, by subject matter, in the Attachment.

Schedule 1 to this Instrument also provides for the 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.

## **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 October 2020.

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

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2020 (No. 8)**

**1 Name**

This section provides that the instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2020 (No. 8)* and may also be cited as PB 91 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 the National Health (Continued Dispensing – Emergency Measures) Determination 2020**

The amendments in Schedule 1 involve the addition and deletion of drugs and the addition and deletion of forms of listed drugs to/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 – EMERGENCY MEASURES) DETERMINATION 2020 MADE BY THIS INSTRUMENT**

**Listed Drugs Added**

**Listed Drug**

Apomorphine

**Listed Drugs Deleted**

**Listed Drug**

Daclatasvir

Danazol

Dipyridamole

**Forms Added**

**Listed Drug**

**Form**

Aflibercept Solution for intravitreal injection 3.6 mg in 90 microlitres (40 mg per mL) pre-filled syringe

Amino acid formula with vitamins and minerals without phenylalanine Sachets containing oral powder 28 g, 30 (PKU Lophlex)

## Forms Deleted

### *Listed Drug*

Dexamethasone

### *Form*

Injection containing dexamethasone sodium phosphate equivalent to 4 mg dexamethasone phosphate in 1 mL

Injection containing dexamethasone sodium phosphate equivalent to 8 mg dexamethasone phosphate in 2 mL

## Documents Incorporated by Reference

### *Document incorporated*

**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

### *Document access*

The PSA Guidelines are freely available from the Pharmaceutical Society of Australia website at [www.psa.org.au/](http://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 – Emergency Measures) Amendment Determination 2020 (No. 8)***

**(PB 91 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 – Emergency Measures) Amendment Determination 2020 (No. 8)* 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 drugs and the addition and deletion of forms of listed drugs to/from the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. 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.

#### **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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