

EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2020 (No. 2)

PB 23 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). This will provide a continued option for consumers to obtain Pharmaceutical Benefits Scheme (PBS) subsidised access to their medicines to assist in managing the demand on the health system during the COVID-19 outbreak. No end date is specified in the instrument, however it is intended to be temporary.

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.

The purpose is also to amend the definition of the “PSA guidelines”, which are the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists*, 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/.

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

The amendment to the definition of “PSA guidelines” in section 1.04 will capture updates made to the PSA guidelines since the commencement of the instrument to provide guidance to assist pharmacists to meet their professional responsibilities, exercise professional judgement in individual circumstances and manage risks associated with the Continued Dispensing of eligible prescribed medicines.

Schedule 1 to this instrument provides for the addition of listed drugs binimetinib and encorafenib and for the addition of a form of the listed drug protein formula with carbohydrate, fat, vitamins and minerals. Additionally, it also provides for the deletion of three listed drugs and for the deletion of a

form of the listed drugs glyceryl trinitrate and ranitidine from the list of pharmaceutical benefits that can 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 April 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. 2)*

1 Name

This section provides that the instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2020 (No. 2)* and may also be cited as PB 23 of 2020.

2 Commencement

This section provides that the instrument commences on 1 April 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 alteration to subsection and 1.04(1), the addition and deletion of drugs and the addition and deletion of forms to the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. These changes are summarised below.

Schedule 1–Amendments

1 Subsection 1.04(1)

Omit “13 January 2020”, and substitute “31 March 2020”

Schedule 1 – Pharmaceutical Benefits

Listed Drugs Added

Listed Drug

Binimetinib

Encorafenib

Listed Drugs Deleted

Listed Drug

Coal tar

Milk powder lactose intolerance formula

Tinidazole

Forms Added

Listed Drug

Protein formula with carbohydrate, fat, vitamins and minerals

Form

Oral liquid 500 mL, 12 (Nutrini Peptisorb Energy)

Forms Deleted

Listed Drug

Glyceryl trinitrate

Ranitidine

Form

Tablets 300 micrograms, 100

Tablet 150 mg (as hydrochloride)

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. 2)

(PB 23 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* 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 involves the alteration to subsection 1.04(1), the addition and deletion of drugs and the addition and deletion of forms to 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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