

EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2020 (No. 9)

PB 105 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.

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 aurothiomalate, pneumococcal vaccine - polyvalent and sofosbuvir and for the deletion of forms of the listed drugs flucloxacillin, glyceryl trinitrate, ketoconazole, nifedipine, periciazine, phenoxybenzamine and quinagolide 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 siponimod and for the addition of a form of the listed drug glycomacropptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine to that list. 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 November 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. 9)

1 Name

This section provides that the instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2020 (No. 9)* and may also be cited as PB 105 of 2020.

2 Commencement

This section provides that the instrument commences on 1 November 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 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

Listed Drugs Added

Listed Drug

Siponimod

Listed Drugs Deleted

Listed Drug

Aurothiomalate

Pneumococcal vaccine - polyvalent

Sofosbuvir

Forms Added

Listed Drug

Glycomacropeptide and essential amino acid formula with vitamins, minerals, and low in tyrosine and phenylalanine

Form

Sachets containing oral powder 31 g, 30 (Tylactin Build 20)

Forms Deleted

Listed Drug

Form

Flucloxacillin

Capsule 250 mg (as sodium)

Capsule 500 mg (as sodium)

Glyceryl trinitrate

Tablets 600 micrograms, 100

Ketoconazole

Shampoo 10 mg per g, 100 mL

Nifedipine

Tablet 20 mg (controlled release)

Periciazine

Tablet 2.5 mg, 84

Tablet 10 mg, 84

Phenoxybenzamine

Capsule containing 10 mg phenoxybenzamine hydrochloride

Quinagolide

Pack containing 3 tablets quinagolide 25 micrograms (as hydrochloride) and 3 tablets quinagolide 50 micrograms (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. 9)

(PB 105 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. 9)* 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 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.

**Paul Hansen
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health**