

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022

PB 119 of 2022

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may, by legislative instrument, determine the pharmaceutical benefits that may be supplied by an approved pharmacist without a prescription, and the conditions that must be satisfied when making a supply of those pharmaceutical benefits.

Purpose

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (Principal Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme (PBS) without a prescription, subject to the conditions specified in the Principal Determination.

The Principal Determination permits an approved pharmacist to supply a substitute pharmaceutical benefit when the pharmaceutical benefit prescribed for the patient is the subject of a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI).

The pharmaceutical benefits containing amoxicillin in the manner of administration oral have been subject to ongoing shortages since July 2022. In response, the TGA has issued the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Amoxicillin) Instrument 2022*, which allows pharmacists to supply different strengths of oral amoxicillin at equivalent doses for the duration of the shortage provided specified conditions are met.

The purpose of the Amendment Determination is to allow PBS subsidisation of the arrangements specified in the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Amoxicillin) Instrument 2022*. The Amendment Determination specifies alternative strengths and brands of amoxicillin that can be supplied without a new prescription in accordance with the specifications and conditions outlined in the SSSI issued by the TGA. This minimises the burden on health care professionals and assists Australians with timely access to antibiotic therapy.

The Amendment Determination permits the supply by an approved pharmacist of any one of the specified substitute pharmaceutical benefits containing the drug amoxicillin in the manner of administration oral in situations where the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989* and it is supplied:

- to a person with a PBS prescription for any one of the specified forms of amoxicillin subject to serious shortages;
- where it is not practicable to obtain a prescription from a PBS prescriber for any one of the specified substitute pharmaceutical benefits before the person needs the supply of amoxicillin;
- by the pharmacist having disclosed information about additional costs to the patient or their agent to that they are able to make an informed decision before proceeding with

the substitute supply; This includes the cost to the patient if the substitution is subsidised through the PBS and the cost to the patient if the substitution is a private prescription; and

- the substitute pharmaceutical benefit containing amoxicillin in the manner of administration oral is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

In order for the specified substitute pharmaceutical benefits to be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*, among other things the pharmacist must:

- advise the patient, or the person acting on behalf of the patient, of the number of dose units, in millilitres or milligrams as applicable, of the substitute medicine containing amoxicillin that must be taken to replace the prescribed pharmaceutical benefit and this must be calculated based on the TGA specified dose unit equivalence;
- ensure that the amount of the substitute pharmaceutical benefit dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to their prescription for the prescribed pharmaceutical benefit; and
- ensure that where multiple bottles of suspension are being dispensed, the treatment course will finish prior to the expiry of the reconstituted bottles.

The Amendment Determination commences on 6 December 2022.

The Amendment Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

A provision-by-provision description of the Amendment Determination is contained in the Attachment.

Consultation

The Amendment Determination reflects the intention of previous consultation.

In relation to the Amendment Determination, consultation was undertaken with the Chair and relevant expert members of the Pharmaceutical Benefits Advisory Committee (PBAC), an independent, expert advisory body that recommends medicines for listing on the PBS. Consultation with PBAC experts focused on specific advice about the appropriateness of PBS subsidisation for the Amendment Determination. The PBAC experts endorsed the proposed approach as it was considered that the substitution arrangement is necessary, with limited other options available for patients during the current shortage needing replacement as quickly as possible.

It is noted the Therapeutic Goods Administration conducted consultation on the appropriateness of the substitutions and consultation on this Amendment Determination was limited to the appropriateness of a PBS subsidy for the substitute medicines. No further consultation was deemed necessary, as consultation with the PBAC Chair drew on the knowledge of relevant experts.

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022*

Section 1 Name

This section provides that the name of the Amendment Determination is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022*.

This section also provides that the Amendment Determination may be cited as PB 119 of 2022.

Section 2 Commencement

This section provides that the Amendment Determination commences on 6 December 2022.

Section 3 Authority

This section provides that the Amendment Determination is made under subsection 89A(3) of the *National Health Act 1953*.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 - Amendments

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021

Item 1 – Subsection 5(8) (at the end of the table)

This item adds the following substitutions to the Schedule:

Prescribed pharmaceutical benefit (medicine subject to short supply)	Substitute pharmaceutical benefit (for the purposes of subsection 89A(3) of the <i>National Health Act 1953</i> , the pharmaceutical benefits that may be supplied without a prescription where the conditions in the Determination are met)
Powder for paediatric oral drops 100 mg (as trihydrate) per 5 mL, 20 mL	<p>Form: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>OR</p> <p>Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p>
Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	<p>Powder for paediatric oral drops 100 mg (as trihydrate) per 5 mL, 20 mL</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>OR</p> <p>Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p>
Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL	<p>Powder for paediatric oral drops 100 mg (as trihydrate) per 5 mL, 20 mL</p> <p>OR</p> <p>Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL</p> <p>OR</p> <p>Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL</p>
Powder for oral suspension 500 mg (as trihydrate) per 5 mL, 100 mL	Powder for paediatric oral drops 100 mg (as trihydrate) per 5 mL, 20 mL

	<p>OR</p> <p>Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A)</p> <p>OR</p> <p>Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL</p>
Capsule 500 mg (as trihydrate)	<p>Capsule 250 mg (as trihydrate)</p> <p>OR</p> <p>Tablet 1 g (as trihydrate)</p>
Tablet 1 g (as trihydrate)	<p>Capsule 250 mg (as trihydrate)</p> <p>OR</p> <p>Capsule 500 mg (as trihydrate)</p>

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022

This Disallowable 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 Disallowable Legislative Instrument

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2022* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (Principal Determination) to specify new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme without a prescription, subject to the conditions specified in the Principal Determination.

The Determination permits an approved pharmacist to supply a substitute pharmaceutical benefit when the pharmaceutical benefit prescribed for the patient is the subject of a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI).

The pharmaceutical benefits containing the drug amoxicillin in the manner of administration oral are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Amoxicillin) Instrument 2022*).

The Amendment Determination specifies that different forms of oral amoxicillin at equivalent doses can be effectively substitutable at the pharmacy level without the need to obtain a new prescription from the prescriber at PBS subsidised prices for the duration of the TGA approval, where conditions in the Principal Determination are met and the supply is in accordance with section 30EL of the *Therapeutic Goods Act 1989*.

This means that eligible patients accessing a substitute pharmaceutical benefit containing amoxicillin under these arrangements will be paying PBS co-payment rates for the supply and will not be out of pocket. This minimises the burden of this shortage on health care professionals by reducing the need for interdisciplinary consultations and assists Australians with timely and equitable access to antibiotic therapy that is considerate of changing availabilities of amoxicillin products. It further bolsters the intended public health outcome of the serious shortage intervention by ensuring the substitution remains an affordable and practical alternative for patients.

Human rights implications

The Amendment Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The Amendment Determination assists in 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 providing subsidised access for people to medicines. This is a positive and supportive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the scheme. The Amendment Determination assists in 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 by ensuring that patients have continued access to their medicines while their supply is disrupted.

Conclusion

The Amendment Determination is compatible with human rights, as it promotes the protection of human rights.

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