

EXPLANATORY STATEMENT

National Health Act 1953

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

PB 84 of 2021

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) Determination 2021* (the Determination) is to permit an approved pharmacist to supply a substitute pharmaceutical benefit when the prescribed pharmaceutical benefit is the subject of a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI). This will support pharmacists in ensuring that consumers who could be adversely affected by medicine shortages may continue to access drugs subsidised through the Pharmaceutical Benefits Scheme (PBS).

The Determination permits the supply by an approved pharmacist of a specified substitute pharmaceutical benefit in situations where the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989* and the substitute pharmaceutical benefit is supplied:

- to a person with a PBS prescription for a pharmaceutical benefit subject to the SSSI;
- where it is not practicable to obtain a PBS prescription from a PBS prescriber for a substitute pharmaceutical benefit before the person needs the supply of the prescribed pharmaceutical benefit;
- where the pharmacist has provided cost information to the patient or their agent so 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 medicine is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

The approved pharmacist is required to record the information set out above justifying supply of the substitute pharmaceutical benefit under the SSSI, in writing, for example in:

- the dispensing system/record
- on the original prescription; or
- on the repeat prescription.

The record must also include that the substitute benefit was supplied under paragraph 89A(3)(a) of the Act.

The pharmacist is also required to notify the relevant PBS prescriber of the details of the substitution in the manner specified in the Determination in writing, for example via fax, email, or secure messaging. The information must be provided to the PBS prescriber within 72 hours after the supply.

Where an authority prescription number is required but not available, the default value of '00000246' should be used. The default authority prescription number may result in a PBS Online warning (reason code 151) which should be disregarded in these circumstances.

The Determination will be re-made or revoked, as appropriate, each time the TGA issues or rescinds a SSSI in respect of a PBS listed drug.

The Determination commences on 16 August 2021.

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

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

Consultation

The Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Australian Medical Association, the Consumers Health Forum of Australia, the Royal Australian College of General Practitioners and the Royal Australian College of Nurse Practitioners were consulted in the development of this Determination.

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

Section 1 Name

This section provides that the name of the Determination is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*.

This section also provides that the instrument may be cited as PB 84 of 2021.

Section 2 Commencement

This section provides that the Determination commences on 16 August 2021.

Section 3 Authority

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

Section 4 Definitions

This section contains defined terms used in the Determination.

Section 5 Supply of pharmaceutical benefits by approved pharmacist without prescription

This section permits an approved pharmacist to supply a substitute pharmaceutical benefit when the prescribed pharmaceutical benefit is subject to a Serious Scarcity Substitution Instrument (SSSI):

- to a person with a PBS prescription for a pharmaceutical benefit and the approved pharmacist cannot supply the pharmaceutical benefit;
- where it is not practicable to obtain a prescription from a PBS prescriber for a substitute drug before the person needs the supply of the prescribed pharmaceutical benefit;
- where the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*; and
- where the pharmacist has enabled the person to make an informed choice by telling the person presenting the script if the supply of the substituted pharmaceutical benefit under the Determination costs the person more than the supply of the prescribed pharmaceutical benefit, and the cost of supply of the substituted drug as a private prescription.

The above cost disclosure condition requires an approved pharmacist to enable the consumer to make an informed decision before proceeding with the substituted supply:

- if the cost to the consumer of being supplied the substituted pharmaceutical benefit under the proposed Determination exceeded the cost to the consumer of being

supplied the prescribed pharmaceutical benefit – that fact, and the difference in cost; and

- if the cost to the consumer of being supplied the substituted pharmaceutical benefit under the proposed Determination exceeded the cost to the consumer of purchasing the substituted drug/s from the pharmacist as a private script – that fact, and the difference in cost.

The approved pharmacist is required to record the information justifying supply of the substitute pharmaceutical benefit and to notify the relevant PBS prescriber of the details of the substitution in the manner specified in the Determination.

From 16 August 2021 and until the TGA revokes its SSSI, the following substitutions of pharmaceutical benefits is permitted under subsection 89A3 of the Act.

Pharmaceutical benefit in shortage	Approved substitute benefit
Tocilizumab, injection 162 mg in 0.9 mL single use pre-filled syringe Actemra Subcutaneous Injection	Tocilizumab, injection 162 mg in 0.9 mL single use pre-filled pen Actemra ACTPen
Tocilizumab, injection 162 mg in 0.9 mL single use pre-filled pen Actemra ACTPen	Tocilizumab, injection 162 mg in 0.9 mL single use pre-filled syringe Actemra Subcutaneous Injection

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) Determination 2021

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 this legislative instrument, made under subsection 89A(3) of the *National Health Act 1953* (the Act), is to permit an approved pharmacist to supply a substitute pharmaceutical benefit when the prescribed pharmaceutical benefit is subject to a Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instrument (SSSI).

The supply of a substitute pharmaceutical benefit is authorised in situations where that where the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989* and:

- to a person with a PBS prescription for a pharmaceutical benefit subject to the SSSMI and the approved pharmacist cannot supply the pharmaceutical benefit;
- where it is not practicable to obtain a prescription from a PBS prescriber for a substitute drug before the person needs the supply of the prescribed drug; and
- where the pharmacist has enabled the person to make an informed choice about the cost of supply of the substituted drug as a pharmaceutical benefit or private prescription.

The approved pharmacist is required to record the information justifying supply of the substitute pharmaceutical benefit and to notify the relevant PBS prescriber of the details of the substitution in the manner specified in the Determination.

Human rights implications

The Determination engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). The 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 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.

Conclusion

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

Nikolai Tsyganov
Acting Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health