



**PB 84 of 2021**

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

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I, Nikolai Tsyganov, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 13 August 2021

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

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## 1 Name

- (1) This instrument is the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*.
- (2) This instrument may also be cited as PB 84 of 2021.

## 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	16 August 2021.	16 August 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

## 3 Authority

This instrument is made under subsection 89A(3) of the *National Health Act 1953*.

## 4 Definitions

Note: The expression premises that is used in this instrument is defined in the Act.

In this instrument:

*Act* means the *National Health Act 1953*.

*approved pharmacist* has the same meaning as in Part VII of the Act.

*listed drug* has the same meaning as in Part VII of the Act.

*PBS prescriber* has the same meaning as in Part VII of the Act.

*pharmaceutical benefit* has the same meaning as in Part VII of the Act.

## 5 Supply of pharmaceutical benefits by approved pharmacist without prescription

- (1) A pharmaceutical benefit (the *substitute benefit*) described in column 2 of an item of the table in subsection (8) may be supplied without a prescription to a person by an approved pharmacist, at or from premises in respect of which the pharmacist is approved, if:
  - (a) a prescription for a pharmaceutical benefit (the *prescribed benefit*) described in column 1 of the item is presented to the approved pharmacist; and
  - (b) subsections (2), (3), (4), (5), (6) and (7) apply.

*Approved pharmacist cannot supply prescribed benefit*

- (2) This subsection applies if the approved pharmacist cannot supply the prescribed benefit.

*Person cannot obtain prescription for substitute benefit in time*

- (3) This subsection applies if the approved pharmacist is satisfied that it is not practicable for the person to obtain a prescription for the substitute benefit from a PBS prescriber before the person needs the supply of the prescribed benefit.

*Substitution permitted under Therapeutic Goods Act*

- (4) This subsection applies if the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*.

*Person presenting prescription has been informed of cost implications*

- (5) This subsection applies if the approved pharmacist has informed the person presenting the prescription of:
  - (a) each substitute benefit that the approved pharmacist can supply instead of the prescribed benefit; and
  - (b) for each substitute benefit that the approved pharmacist can supply:
    - (i) the amount (which may be a nil amount) that the approved pharmacist would, if the approved pharmacist supplied the substitute benefit to the person for whom the prescribed benefit was prescribed, be permitted by Part VII of the Act to charge that person for that supply; and
    - (ii) the amount that the approved pharmacist would, if the approved pharmacist supplied the substitute benefit otherwise than under Part VII of the Act to the person for whom the prescribed benefit was prescribed, charge that person for that supply; and
  - (c) the amount (which may be a nil amount) that the approved pharmacist would, if the approved pharmacist supplied the prescribed benefit to the person for whom it was prescribed, be permitted by Part VII of the Act to charge that person for that supply.

*Record of information justifying supply of substitute benefit*

- (6) This subsection applies if the approved pharmacist records the information that the approved pharmacist used to support the decision to supply the substitute benefit, including the following statements:
- (a) a statement that the substitute benefit supplied is a pharmaceutical benefit determined under paragraph 89A(3)(a) of the Act;
  - (b) a statement that the conditions in this section are satisfied;
  - (c) a statement that the approved pharmacist is satisfied that the substitute benefit needs to be supplied because:
    - (i) the approved pharmacist cannot supply the prescribed benefit; and
    - (ii) it is not practicable for the person to obtain a prescription for the substitute benefit from a PBS prescriber before the person needs the supply of the prescribed benefit.

*Arrangements to inform PBS prescriber of substitution*

- (7) This subsection applies if the approved pharmacist has in place arrangements for giving, to the PBS prescriber who wrote the prescription for the prescribed benefit, written notice of the supply of the substitute benefit, within 72 hours after that supply.

*Table of prescribed and substitute pharmaceutical benefits*

- (8) For the purposes of subsection (1), the table is as follows.

<b>Prescribed and substitute pharmaceutical benefits</b>		
<b>Item</b>	<b>Column 1 Prescribed pharmaceutical benefit</b>	<b>Column 2 Substitute pharmaceutical benefit</b>
1	Listed drug: Tocilizumab Form: Injection 162 mg in 0.9 mL single use pre-filled syringe Manner of administration: Injection Brand: Actemra Subcutaneous Injection	Listed drug: Tocilizumab Form: Injection 162 mg in 0.9 mL single use pre-filled pen Manner of administration: Injection Brand: Actemra ACTPen
2	Listed drug: Tocilizumab Form: Injection 162 mg in 0.9 mL single use pre-filled pen Manner of administration: Injection Brand: Actemra ACTPen	Listed drug: Tocilizumab Form: Injection 162 mg in 0.9 mL single use pre-filled syringe Manner of administration: Injection Brand: Actemra Subcutaneous Injection