

# EXPLANATORY STATEMENT

*National Health Act 1953*

## ***National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2022***

**PB 10 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. 1) 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). Following ongoing intermittent shortages of abatacept, the TGA has issued the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 2022*, which allows pharmacists to supply Orencia ClickJect when presented with a valid prescription for Orencia and vice versa for the duration of the shortage provided the conditions specified by the TGA are met.

Orencia ClickJect and Orencia are currently PBS subsidised with a Dispensed Price per Maximum Quantity of \$958.82 per dispensing. While the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 2022* allows for patients to receive a clinically equivalent substitute without needing a new prescription, it does not allow PBS subsidised supply of the substitute. This means that instead of paying their usual PBS co-payments (\$6.80 for concessional patients and \$42.50 for general patients), patients may need to pay up to \$958.82 for each supply, which could result in such an arrangement being unaffordable and impractical.

The purpose of the Amendment Determination is to allow PBS subsidisation of the arrangements specified in the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Instrument 2022*. The Amendment Determination provides that Orencia ClickJect or Orencia may be supplied at the PBS co-payment rate to eligible patients when supplied at the discretion of the pharmacist. This allows for continuation of treatment in these patient groups for the duration of the expected supply shortages.

The Principal 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 Principal 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. Pharmacists are required to use the Authority prescription number annotated on the existing prescriptions for abatacept products and disregard PBS Online warnings (reason code 162 and 163) in these circumstances.

The Principal 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 Amendment Determination commences on **8 February 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.

Consultation was previously undertaken with stakeholders in the development of the Principal Determination. Consultation focused on PBS subsidisation of medicines substituted in accordance with section 30EL of the *Therapeutic Goods Act 1989*.

Stakeholders included, 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. Stakeholders were supportive of the Principal Determination. Stakeholders raised no substantive concerns in relation to the Principal Determination, however they requested improved communication strategies, which the Department undertook in response.

Consultation with stakeholders on PBS subsidy was undertaken in the development of the Principal Determination. As the Amendment Determination reflects the intention of that previous consultation, no further industry stakeholder consultation was considered necessary.

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.

## ATTACHMENT

### **Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) 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. 1) Determination 2022*.

This section also provides that the Amendment Determination may be cited as PB 10 of 2022.

#### **Section 2 Commencement**

This section provides that the Amendment Determination commences on 8 February 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 sets out that the amendments to be made to the Principal Determination are in Schedule 1. The amendments include the addition of abatacept injection 125 mg in 1 mL single dose autoinjector (Orencia ClickJect) and abatacept injection 125 mg in 1 mL single dose pre-filled syringe (Orencia) as pharmaceutical benefits in shortage and specifies approved substitute benefits to be supplied at PBS subsidised prices for the duration of the TGA approval.

#### **Schedule 1 - Amendments**

This item adds two new items to the table at subsection 5(8) of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*:

<b>Item</b>	<b>Column 1 Prescribed pharmaceutical benefit</b>	<b>Column 2 Substitute pharmaceutical benefit</b>
6	Listed drug: Abatacept Form: Injection 125 mg in 1 mL single dose autoinjector Manner of administration: Injection Brand: Orencia ClickJect	Listed drug: Abatacept Form: Injection 125 mg in 1 mL single dose pre-filled syringe Manner of administration: Injection Brand: Orencia
7	Listed drug: Abatacept Form: Injection 125 mg in 1 mL single dose pre-filled syringe Manner of administration: Injection Brand: Orencia	Listed drug: Abatacept Form: Injection 125 mg in 1 mL single dose autoinjector Manner of administration: Injection Brand: Orencia ClickJect

Column 1 of this table sets out the pharmaceutical benefits that may be supplied without a prescription under subsection 89A(3) of the *National Health Act 1953*, where the conditions in the Principal Determination are met.

## **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. 1) 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. 1) 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 Amendment Determination specifies that abatacept 125 mg in 1 mL single dose autoinjector and single dose pre-filled syringe can be supplied interchangeably at the PBS subsidised price, where conditions in the Principal Determination are met. This means that eligible patients accessing the substitute product under these arrangements will be paying PBS co-payment rates for the supply and will not be out of pocket. This 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.

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