

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 3) Determination 2022

PB 73 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. 3) 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 implement the Therapeutic Goods Administration (TGA) decision to revoke pharmacist substitution of some benefits.

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 TGA Serious Scarcity Substitution Instrument (SSSI). The Principal Determination incorporated the TGA arrangements to permit pharmacist substitution of abatacept injection 125 mg in 1 mL single dose autoinjector and single dose pre-filled pen in brands Orenzia and Orenzia ClickJect, consistent with the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Amendment Instrument 2022*.

The *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Abatacept) Amendment Instrument 2022* was in force until 30 June 2022. Approved pharmacists are no longer permitted to supply the nominated substitute pharmaceutical benefits in place of the prescribed pharmaceutical benefits without a prescription.

Patients will continue to be able to access abatacept injection 125 mg in 1 mL single dose autoinjector and single dose pre-filled pen at PBS subsidised prices but will be required to have the correct pharmaceutical benefits written on their prescriptions.

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

The Amendment Determination commences on **1 August 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.

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 3) 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. 3) Determination 2022*.

This section also provides that the instrument may be cited as PB 73 of 2022.

Section 2 Commencement

This section provides that the Amendment Determination commences on 1 August 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)

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

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

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. 3) 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. 3) 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 revoke pharmacist substitution of specified pharmaceutical benefits as they are no longer subject to Therapeutic Goods Administration (TGA) Serious Scarcity Substitution Instruments (SSSIs). This is being done following the resolution of shortages of abatacept injection 125 mg in 1 mL single dose autoinjector and single dose pre-filled pen in the brands Orencia and Orencia ClickJect.

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 Amendment Determination does not impact equitable access to medicines as abatacept injection 125 mg in 1 mL single dose autoinjector and single dose pre-filled pen in the brands Orencia and Orencia ClickJect continue to be available at PBS subsidised prices for patients with prescriptions written for these pharmaceutical benefits.

Conclusion

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

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