

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) Determination 2022

PB 42 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. 2) 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 products, tocilizumab 162 mg in 0.9 ml single use pre-filled syringe and single use pre-filled pen in brands Actemra Subcutaneous Injection and Actemra ACTPen and tablet containing estradiol valerate in 1 mg and 2 mg strengths in brands Progynova and Zumenon.

The TGA revoked the SSSI for tocilizumab on 30 April 2022 and the SSSI for estradiol valerate on 1 May 2022 following the resolution of shortages of tocilizumab 162 mg in 0.9 ml single use pre-filled syringe in the brand Actemra Subcutaneous Injection, tocilizumab single use pre-filled pen in the brand Actemra ACTPen and tablet containing estradiol valerate in strengths 1 mg and 2 mg and brand Progynova. Following this change, approved pharmacists are no longer permitted to supply the nominated substitute pharmaceutical benefits in place of the prescribed pharmaceutical benefits without a prescription. The Amendment Determination implements the TGA amendments to PBS subsidy arrangements.

Patients will continue to be able to access tocilizumab 162 mg in 0.9 ml single use pre-filled syringe, tocilizumab single use pre-filled pen and tablet containing estradiol valerate in strengths 1 mg and 2 mg at PBS subsidised prices.

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 **20 May 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 consultation with the TGA.

No additional consultation with experts was undertaken regarding this determination because consultation with the TGA and the affected responsible persons drew on the knowledge of persons with relevant expertise.

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 2) 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. 2) Determination 2022*.

This section also provides that the instrument may be cited as PB 42 of 2022.

Section 2 Commencement

This section provides that the Amendment Determination commences on 20 May 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 four items from the table at subsection 5(8) of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021*:

	Column 1 Prescribed pharmaceutical benefit	Column 2 Substitute pharmaceutical benefit
1	Listed drug: Tocilizumab	Listed drug: Tocilizumab
	Form: Injection 162 mg in 0.9 mL single use pre-filled syringe	Form: Injection 162 mg in 0.9 mL single use pre-filled pen
	Manner of administration: Injection	Manner of administration: Injection
	Brand: Actemra Subcutaneous Injection	Brand: Actemra ACTPen
2	Listed drug: Tocilizumab	Listed drug: Tocilizumab
	Form: Injection 162 mg in 0.9 mL single use pre-filled pen	Form: Injection 162 mg in 0.9 mL single use pre-filled syringe
	Manner of administration: Injection	Manner of administration: Injection
	Brand: Actemra ACTPen	Brand: Actemra Subcutaneous Injection
3	Listed drug: Estradiol	Listed drug: Estradiol
	Form: Tablet containing estradiol valerate 1 mg	Form: Tablet 2 mg
	Manner of administration: Oral	Manner of administration: Oral
	Brand: Progynova	Brand: Zumenon
4	Listed drug: Estradiol	Listed drug: Estradiol
	Form: Tablet containing estradiol valerate 2 mg	Form: Tablet 2 mg
	Manner of administration: Oral	Manner of administration: Oral
	Brand: Progynova	Brand: Zumenon

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. 2) 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. 2) 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 reflects the resolution of shortages of tocilizumab 162 mg in 0.9 ml single use pre-filled syringe in the brand Actemra Subcutaneous Injection, tocilizumab single use pre-filled pen in the brand Actemra ACTPen and tablet containing estradiol valerate in 1 mg and 2 mg strengths in the brand Progynova.

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.

The Amendment Determination does not impact equitable access to medicines as tocilizumab 162 mg in 0.9 ml single use pre-filled syringe, tocilizumab single use pre-filled pen and tablet containing estradiol valerate in 1 mg and 2 mg strengths continue to be available at PBS subsidised prices.

Conclusion

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

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