

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 5) Determination 2024

PB 137 of 2024

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. 5) Determination 2024* (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).

Novo Nordisk, the sponsor of Protaphane InnoLet brand containing insulin isophane injection has informed the TGA that it will discontinue the subject brand from the market by 1 February 2025. In response, the TGA has issued the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin isophane) Instrument 2024*, which allows pharmacists to supply a different brand of insulin isophane injection at equivalent doses for the duration of the shortage provided specified conditions are met.

The purpose of the Amendment Determination is to allow PBS subsidisation of the arrangements that will be specified in the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin isophane) Instrument 2024*. The Amendment Determination will specify that a different brand of insulin isophane injection at equivalent doses can be supplied without a new prescription in accordance with the specifications and conditions outlined in the SSSI issued by the TGA. This minimises the burden on health care professionals and assist with timely access to medicine supply for patients.

The Amendment Determination permits the supply by an approved pharmacist of the specified substitute pharmaceutical benefit containing the drug insulin isophane in the manner of injection administration in situations where the substitute benefit may be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989* and it is supplied:

- to a person with a PBS prescription for the specified form of insulin isophane subject to serious shortages;

- where it is not practicable to obtain a prescription from a PBS prescriber for the specified substitute pharmaceutical benefits before the person needs the supply of insulin isophane;
- by the pharmacist having disclosed information about additional costs to the patient or their agent to 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 pharmaceutical benefit containing insulin isophane in the manner of injection administration is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

In order for the specified substitute pharmaceutical benefits to be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*, among other things, the pharmacist must:

- ensure the patient, or person acting on behalf of the patient, has, or is given, a suitable insulin delivery system to administer the substitutable medicine.
- advise the patient, or person acting on behalf of the patient:
 - of suitable instructions for administering the substitutable medicine, including using the insulin delivery system; or
 - where the pharmacist is unable to provide suitable instructions—to obtain suitable instructions for administering the substitutable medicine, including using the insulin delivery system, from the prescriber, a suitably qualified health practitioner or a credentialed diabetes educator; and
- advise the patient, or person acting on behalf of the patient, of the number of dose units of substitutable medicine that must be administered to the patient in substitution for the prescribed dose of scarce medicine, based on the dose unit equivalence specified.
- advise the patient, or person acting on behalf of the patient, of the differences between the scarce medicine and substitutable medicine

The Amendment Determination commences on 16 December 2024.

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.

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.

It is noted the TGA conducted consultation on the appropriateness of the substitutions and consultation on this Amendment Determination was limited to the appropriateness of a PBS subsidy for the substitute medicines. No further consultation was deemed necessary, as consultation with the PBAC Chair drew on the knowledge of relevant experts.

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 5) Determination 2024*

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. 5) Determination 2024*.

This section also provides that the Amendment Determination may be cited as PB 137 of 2024.

Section 2 Commencement

This section provides that the Amendment Determination commences on 16 December 2024.

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.

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. 5) Determination 2024

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. 5) Determination 2024* (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 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).

The pharmaceutical benefits containing the drug insulin isophane in the manner of injection administration are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin isophane) Instrument 2024*).

The Amendment Determination specifies that a different brand of insulin isophane injection at equivalent dose can be effectively substitutable at the pharmacy level without the need to obtain a new prescription from the prescriber at PBS subsidised prices for the duration of the TGA approval, where conditions in the Principal Determination are met and the supply is in accordance with section 30EL of the *Therapeutic Goods Act 1989*.

This means that eligible patients accessing a substitute pharmaceutical benefit containing insulin isophane under these arrangements will be paying PBS co-payment rates for the supply and will not be out of pocket. This minimises the burden of this shortage on health care professionals by reducing the need for interdisciplinary consultations and assists Australians with timely and equitable access to medicine supply for patients that is considerate of changing availabilities of insulin isophane injection. It 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 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.

Eden Simon
Acting Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care