

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2023

PB 66 of 2023

Purpose

The purpose of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2023* (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).

The pharmaceutical benefits containing insulin degludec with insulin aspart in the manner of administration injection have been subject to ongoing shortages since June 2023. In response, the TGA is working on issuing the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec and Insulin Aspart) Instrument 2023*, which allows pharmacists to supply a different form of insulin degludec with insulin aspart 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 Degludec and Insulin Aspart) Instrument 2023*. The Amendment Determination will specify that a different form of insulin degludec with insulin aspart injection at the same dosage 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 assists Australians with timely access to medicine supply for patients.

The Amendment Determination permits the supply by an approved pharmacist of any one of the specified substitute pharmaceutical benefits containing the drug insulin degludec with insulin aspart injection in the manner of administration injection 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 degludec with insulin aspart 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 degludec with insulin aspart;
- 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 in the injection manner of 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:

- a) 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; and
- b) advise the patient, or person acting on behalf of the patient:
 - i. of suitable instructions for administering the substitutable medicine, including using the insulin delivery system; or
 - ii. 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
- c) 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, which is one 3 mL (300 unit) cartridge of the substitutable medicine is equivalent to one 3 mL (300 unit) pre-filled pen of the scarce medicine; and
- d) advise the patient, or person acting on behalf of the patient, of the differences between the scarce medicine and substitutable medicine

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.

Commencement

The Amendment Determination commences on 6 July 2023.

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 Therapeutic Goods Administration 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.

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.

ATTACHMENT

Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 4) Determination 2023*

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. 4) Determination 2023*.

This section also provides that the Amendment Determination may be cited as PB 66 of 2023.

Section 2 Commencement

This section provides that the Amendment Determination commences on 6 July 2023.

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) (at the end of the table)

This item adds the following substitutions to the Schedule:

Prescribed pharmaceutical benefit (medicine subject to short supply)	Substitute pharmaceutical benefit (for the purposes of subsection 89A(3) of the <i>National Health Act 1953</i> , the pharmaceutical benefits that may be supplied without a prescription where the conditions in the Determination are met)
Injections, pre-filled pen, 70 units-30 units per mL, 3 mL, 5	Injections, cartridges, 70 units-30 units per mL, 3 mL, 5

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. 4) Determination 2023

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. 4) Determination 2023* (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 degludec with insulin aspart in the manner of administration oral are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Insulin Degludec with Insulin Aspart) Instrument 2023*).

The Amendment Determination specifies that a different form of insulin degludec with insulin aspart injection at the 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 degludec with insulin aspart 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 degludec with insulin aspart products. 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.

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