

## EXPLANATORY STATEMENT

*National Health Act 1953*

### ***National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2021***

**PB 95 of 2021**

#### **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 2021* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (the 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 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 relating to the Prognyoova brand of the drug estradiol (1 mg and 2 mg tablet forms) are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Estradiol Valerate) Instrument 2021*). The Amendment Determination specifies an alternative brand of estradiol, Zumenon in a 2 mg tablet form (Zumenon (estradiol) 2 mg), that can be supplied without a prescription in substitution for Prognyoova (estradiol valerate) 1 mg or 2 mg.

As a result, the Determination permits the supply by an approved pharmacist of Zumenon (estradiol) 2 mg where Zumenon (estradiol) 2 mg 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 Prognyoova (estradiol valerate) 1mg or 2 mg;
- where it is not practicable to obtain a PBS prescription from a PBS prescriber for Zumenon (estradiol) 2 mg before the person needs the supply of the Prognyoova (estradiol valerate) 1 mg or 2 mg;
- 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 supply of Zumenon (estradiol) 2 mg. 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
- Zumenon (estradiol) 2 mg is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

In order for Zumenon (estradiol) 2 mg to be dispensed in accordance with section 30EL of the *Therapeutic Goods Act 1989*, among other things the pharmacist must:

- Ensure that the amount of Zumenon (estradiol) 2 mg dispensed would result in the patient receiving sufficient medicine to ensure an equivalent dosage regimen and duration to their prescription for Progynova (estradiol valerate) 1 mg or 2 mg;
- Advise the patient or their agent of the number of dose units of Zumenon (estradiol) 2 mg that must be taken by the patient in substitution for the prescribed dose of Progynova (estradiol valerate) 1 mg or 2 mg (as appropriate); and
- Where cutting of a tablet of Zumenon (estradiol) 2 mg is required to obtain the correct dose—instruct the patient on how to cut the tablet, as the Zumenon (estradiol) 2 mg tablet is unscored.

The Amendment Determination commences on 20 August 2021.

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.

**Details of the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Amendment (No. 1) Determination 2021***

**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 2021*.

This section also provides that the instrument may be cited as PB 95 of 2021.

**Section 2 Commencement**

This section provides that the Amendment Determination commences on 20 August 2021.

**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 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>Column 2 Pharmaceutical benefit in shortage</b>	<b>Column 3 Approved substitute benefit</b>
3	Listed drug: Estradiol, Form: tablet containing estradiol valerate 1 mg Manner of administration: Oral Brand: Progynova	Listed drug: Estradiol Form: Tablet 2 mg Manner of administration: Oral Brand: Zumenon
4	Listed drug: Estradiol Form: Tablet containing estradiol valerate 2 mg Manner of administration: Oral Brand: Progynova	Listed drug: Estradiol Form: Tablet 2 mg Manner of administration: Oral Brand: Zumenon

Column 3 of this table sets out, for the purposes of subsection 89A(3) of the *National Health Act 1953*, the pharmaceutical benefits that may be supplied without a prescription where the conditions in the 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 2021***

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 2021* (Amendment Determination) is to amend the *National Health (Pharmaceutical Benefits) (Pharmacist Substitution of Medicines without Prescription during Shortages) Determination 2021* (the Determination) to specify two new pharmaceutical benefits that may be supplied under the Pharmaceutical Benefits Scheme without a prescription, subject to the conditions specified in the 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 relating to the Prognyoova brand of the drug estradiol (1 mg and 2 mg tablet forms) are currently subject to an SSSI (see the *Therapeutic Goods (Serious Scarcity and Substitutable Medicine) (Estradiol Valerate) Instrument 2021*).

The Amendment Determination specifies an alternative brand of estradiol, Zumenon in a 2 mg tablet form (Zumenon (estradiol) 2 mg), that can be supplied without a prescription in substitution for Prognyoova (estradiol valerate) 1 mg or 2 mg where the conditions in the Determination are met.

These include that the supply by an approved pharmacist of Zumenon (estradiol) 2 mg is in accordance with section 30EL of the *Therapeutic Goods Act 1989* and it is supplied:

- to a person with a PBS prescription for the Prognyoova (estradiol valerate) 1mg or 2 mg;
- where it is not practicable to obtain a PBS prescription from a PBS prescriber for Zumenon (estradiol) 2 mg before the person needs the supply of the Prognyoova (estradiol valerate) 1 mg or 2 mg;
- 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 supply of Zumenon (estradiol) 2 mg. 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
- Zumenon (estradiol) 2 mg is eligible for dispensing as a pharmaceutical benefit as outlined in this instrument.

## **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 medicines.

## **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**