

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2025 (No. 10)*

#### **PB 123 of 2025**

#### **Purpose**

The purpose of the *National Health (Pharmaceutical benefits—early supply) Amendment Instrument 2025 (No. 10)* (Instrument) is to amend the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* (PB 120 of 2015) (Principal Instrument).

PB 120 of 2015 specifies the pharmaceutical items that are in pharmaceutical benefits for which the Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following previous supply that is the ‘early supply period’.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (the Listing Instrument), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), and amendments to that instrument, are made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act).

#### **Authority**

Subsection 84AAA(1) of the Act provides that a supply of a pharmaceutical benefit (whether or not the supply is of a kind described in paragraph 84C(4A)(a) of the Act) to a person is an early supply of a specified pharmaceutical benefit if:

- (a) The pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2); and
- (b) the supply is made within the relevant ‘early supply period’ after the day of a previous relevant supply to the person of:
  - (i) the same pharmaceutical benefit; or
  - (ii) another pharmaceutical benefit that has the same pharmaceutical item as the pharmaceutical benefit; or
  - (iii) another pharmaceutical benefit that is Schedule equivalent to the pharmaceutical benefit; and
- (c) the supply does not result from a prescription originating from a hospital.

Subsection 84AAA(2) of the Act provides that the Minister may specify, by legislative instrument, pharmaceutical items for the purposes of paragraph 84AAA(1)(b) of the Act.

Subsection 84AAA(3) provides that the instrument may specify a pharmaceutical item by reference to the circumstances in which a pharmaceutical benefit that has the pharmaceutical item is supplied or any other circumstances in relation to a pharmaceutical benefit that has the pharmaceutical item.

Paragraph 84C(4A) of the Act refers to repatriation pharmaceutical benefits supplied under the schemes established under section 91 of the *Veterans’ Entitlements Act 1986* or section 18 of the *Australian Participants in British Nuclear Tests and British Commonwealth Occupation Force (Treatment) Act 2006* or supplied in accordance with a determination made under paragraph 286(1)(c) of the *Military Rehabilitation and Compensation Act 2004*.

Subsection 101(3AA) of the Act requires the Pharmaceutical Benefits Advisory Committee (PBAC) to make recommendations to the Minister about what should be specified in the instrument under subsection 84AAA(2).

## **Changes to PB 120 of 2015 made by this Instrument**

The amendments made by this Instrument include the addition of the drugs elafibranor and etonogestrel with ethinylestradiol, the addition of forms of the listed drugs brexpiprazole and clopidogrel, and the deletion of forms of the listed drugs estradiol with norethisterone and ethosuximide for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 20 days after the day of a previous relevant supply (Schedule 1 to the Principal Instrument). It also provides for the addition of forms of the listed drug clopidogrel, the deletion of the listed drug betaxolol, and the deletion of forms of the listed drug estradiol with norethisterone, for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 50 days after the day of a previous relevant supply (Schedule 2 to the Principal Instrument).

These changes are summarised by subject matter in the Attachment.

## **Variation and revocation**

Unless there is an express power to revoke or vary PB 120 of 2015 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 120 of 2015.

## **Consultation**

The involvement of PBAC constitutes a formal and ongoing process of consultation. The PBAC is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. The Committee also includes a pharmaceutical industry nominee. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the Committee. The PBAC has provided advice regarding what should be specified in this Instrument.

This amendment is minor and machinery in nature.

## **General**

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 November 2025.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

**PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2025 (No. 10)**

**Section 1 Name of Instrument**

This section provides that the name of the Instrument is the *National Health (Pharmaceutical benefits—early supply) Amendment Instrument 2025 (No. 10)* (Instrument) and may also be cited as PB 123 of 2025.

**Section 2 Commencement**

This section provides that the Instrument commences on 1 November 2025.

**Section 3 Authority**

This section provides that the Instrument is made under subsection 84AAA(2) of the *National Health Act 1953* (Act).

**Section 4 Schedules**

This section provides that each instrument specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule, and any other item in a Schedule has effect according to its terms.

**Schedule 1 Amendments**

The amendments in Schedule 1 involve the addition of drugs, and the addition and deletion of forms of listed drugs for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies made within 20 days after the day of a previous relevant supply (Schedule 1 to the Principal Instrument), and the deletion of a listed drug, and the addition and deletion of forms of listed drugs for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 50 days after the day of a previous relevant supply (Schedule 2 to the Principal Instrument). These changes are summarised below.

**SUMMARY OF CHANGES TO THE NATIONAL HEALTH (PHARMACEUTICAL BENEFITS—EARLY SUPPLY) INSTRUMENT 2015 MADE BY THIS INSTRUMENT**

**Drug Addition - Schedule 1**

**Listed Drug**

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Elafibranor

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Etonogestrel with ethinylestradiol

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**Form Addition - Schedule 1**

**Listed Drug**

**Form**

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Brexiprazole

Tablet 500 micrograms

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Clopidogrel

Tablet 75 mg (as bisulfate) (Aurobindo, USA) (S19A)

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Tablet 75 mg (as bisulfate) (Novadoz, USA) (S19A)

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Tablet 75 mg (as hydrogen sulfate) (S19A)

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## Form Deletion - Schedule 1

<i>Listed Drug</i>	<i>Form</i>
Estradiol with norethisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)
	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)
Ethosuximide	Capsule 250 mg (s19A)

## Drug Deletion - Schedule 2

### *Listed Drug*

Betaxolol

## Form Addition - Schedule 2

<i>Listed Drug</i>	<i>Form</i>
Clopidogrel	Tablet 75 mg (as bisulfate) (Aurobindo, USA) (S19A)
	Tablet 75 mg (as bisulfate) (Novadoz, USA) (S19A)
	Tablet 75 mg (as hydrogen sulfate) (S19A)

## Form Deletion - Schedule 2

<i>Listed Drug</i>	<i>Form</i>
Estradiol with norethisterone	Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A)
	Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A)

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2025 (No. 10)***

**(PB 123 of 2025)**

This 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 Legislative Instrument**

The *National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2025 (No. 10)* (the Instrument) amends the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* (PB 120 of 2015) (the Principal Instrument), which specifies pharmaceutical benefits that have an ‘early supply’ period for the purposes of section 84AAA of the *National Health Act 1953*, and the respective benefits’ “early supply” periods (days elapsed since previous supply), for which Pharmaceutical Benefits Scheme (PBS) Safety Net entitlements will not apply for early supplies.

The effect of a pharmaceutical benefit being an early supply is that the patient payment for that prescription does not count towards the PBS safety net threshold, and, if the PBS safety net threshold has been reached and the operation of the PBS safety net would normally allow a concessional or nil contribution for the prescription, the patient payment and the amount paid by the Commonwealth to the pharmacy or other approved supplier revert to pre-PBS safety net amounts.

Schedule 1 to the Principal Instrument specifies pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 20 days after the day of a previous relevant supply. Schedule 2 to the Principal Instrument specifies pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made:

- where the previous relevant supply was on the basis of a prescription written for 60 days’ supply - within 50 days after the day of that previous supply; and
- in any other case – within 20 days of that previous supply.

### **Human rights implications**

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

#### *The Right to Social Security*

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (ICESCR). It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights (the Committee) reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

## *The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

### **Analysis**

This Instrument engages the right to health and the right to social security because drugs listed in this Instrument mean that safety net benefits will not apply for resupplies of these medicines when they are obtained earlier than:

- for pharmaceutical benefits specified in Schedule 1 and where the circumstances in section 6 of the Principal Instrument apply – 20 days from the previous supply; and
- for pharmaceutical benefits specified in Schedule 2 and where the circumstances in section 7 of the Principal Instrument apply – 50 days from the previous supply if the previous supply to the person was on the basis of a prescription written for an increased maximum dispensed quantity equivalent to 60 days’ supply, and 20 days in other circumstances. This means that where a patient is moving to a 60 days prescription for the first time, they are still only subject to a 20 days early supply period.

This limitation is reasonable, necessary and proportionate, as early supply arrangements support the quality use of medicines and responsible use of PBS entitlements as well as discouraging waste and reducing the quantity of unused medicines in the community. The listing of new and innovative medicines relies on using PBS funding responsibly and keeping the PBS sustainable.

The PBS is a benefit scheme which assists with advancement of these human rights by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The amendments made by this Instrument include the addition of the drugs elafibranor and etonogestrel with ethinylestradiol, the addition of forms of the listed drugs brexpiprazole and clopidogrel, and the deletion of forms of the listed drugs estradiol with norethisterone and ethosuximide for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 20 days after the day of a previous relevant supply (Schedule 1 to the Principal Instrument). It also provides for the addition of forms of the listed drug clopidogrel, the deletion of the listed drug betaxolol, and the deletion of forms of the listed drug estradiol with norethisterone, for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies where the supply is made within 50 days after the day of a previous relevant supply (Schedule 2 to the Principal Instrument), to reflect amendments made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) (the Listing Instrument).

The Listing Instrument determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug

will result in an unmet clinical need for patients. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Listing Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of a drug, and forms of listed drugs in the above-mentioned instruments would not result in an unmet clinical need, except where indicated for a particular form listed below. Where the PBAC has identified an unmet clinical need, a Supply Only period will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2024, these amounts are \$31.60 for general patients and \$7.70 for concession card holders.

The drug estradiol with norethisterone in each of the forms transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 (S19A) and transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 (S19A) were requested to be delisted from the PBS schedule following agreement from the sponsor. The temporary approval under section 19A of the *Therapeutic Goods Act 1989* granted by the Therapeutic Goods Administration in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 July 2025. Patient access has not been affected as the Australian Register of Therapeutic Goods approved forms of the drug are now available and remain PBS subsidised and accessible for patients.

The drug ethosuximide in the form capsule 250 mg (s19A) was requested to be delisted from the PBS schedule following agreement from the sponsor. The temporary approval under section 19A of the *Therapeutic Goods Act 1989* granted by the Therapeutic Goods Administration in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 31 July 2025. Patient access has not been affected as the Australian Register of Therapeutic Goods approved forms of the drug are now available and remain PBS subsidised and accessible for patients.

## **Conclusion**

This Instrument is compatible with human rights because it advances the protection of human rights.

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