EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2022 (No. 9)

PB 86 of 2022

Purpose

The purpose of this legislative instrument, made under subsection 84AAA(2) of the *National Health Act 1953* (the Act) is to amend the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* (PB 120 of 2015) (the Principal Instrument).

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

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of 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 20 days after the day of a previous 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 (Treatment) Act 2006* or supplied in accordance with a determination made under paragraph 256(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

Schedule 1 to this instrument provides for the deletion of the listed drug alendronic acid with colecalciferol and calcium, and for the deletion of forms of the listed drug nifedipine. It also provides for the addition of the listed drugs decitabine with cedazuridine, and trientine, the addition of a maximum quantity and number of repeats for the listed drug enzalutamide, and the addition of a form of the listed drugs ethosuximide, and fremanezumab for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies.

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 October 2022.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT INSTRUMENT 2022 (No. 9)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2022 (No. 9)* and may also be cited as PB 86 of 2022.

Section 2 Commencement

This section provides that the Instrument commences on 1 October 2022.

Section 3 Authority

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

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition and deletion of listed drugs, the addition and deletion of forms of listed drugs, and the addition of a maximum quantity and number of repeats for a listed drug for the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies. These changes are summarised below.

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

Listed Drug Deleted

Listed Drug

Alendronic acid with colecalciferol and calcium

Listed Drugs Added

Listed Drug

Decitabine with cedazuridine

Trientine

Forms Added

Listed Drug	***Form***
Ethosuximide	Capsule 250 mg (s19A)
Fremanezumab	Solution for injection 225 mg in 1.5 mL single dose pre-filled pen

Forms Deleted

Listed Drug	*Form*
Nifedipine	Tablet 10 mg
	Tablet 20 mg

Addition of Maximum Quantity and Number of Repeats

Listed Drug	*Form*	*Maximum Quantity*	*Number of Repeats*
Enzalutamide	Capsule 40 mg	112	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 – early supply) Amendment Instrument 2022 (No. 9)

(PB 86 of 2022)

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 2022 (No. 9)* (the Instrument) amends the *National Health (Pharmaceutical benefits—early supply) Instrument 2015* (PB 120 of 2015) (the Principal Instrument) which 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.

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

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 20 days from the previous supply. 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 patients subsidised access 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.

This Instrument provides for the addition of the listed drugs decitabine with cedazuridine, and trientine and the addition of a form of the listed drugs ethosuximide, and fremanezumab to the list of pharmaceutical benefits for which PBS safety net entitlements will not apply for early supplies, to reflect amendments made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument).

The drug alendronic acid with colecalciferol and calcium was requested to be delisted from the PBS by the sponsor due to the discontinuation of the product from 1 December 2021. The PBAC considered that although this is the last combination product of alendronate, vitamin D and calcium, there are suitable alternatives in separate forms available. The PBAC advised the delisting of alendronate with colecalciferol and calcium would not result in an unmet clinical need. This item was available on the PBS under supply only arrangements for a period of up to 6 months, which provided patients with an existing valid prescription continued access to this item after it was removed for prescribing purposes.

The drug nifedipine in the forms tablet 10 mg (Adefin® 10) and tablet 20 mg (Adefin® 20) were requested to be delisted from the PBS by the sponsor due to its intention to discontinue supply of the products in Australia. The PBAC advised that the delisting of both forms from the PBS may result in an unmet clinical need. The Department contacted the sponsor and sought to retain the product in line with this advice, however the sponsor indicated retention was not possible due to the product being discontinued from manufacture and that it wished to proceed with the delisting.

Conclusion

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

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