EXPLANATORY STATEMENT

National Health Act 1953

National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024

PB 110 of 2024

Purpose and operation

The *National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024* (PB 110 of 2024) (Instrument) amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (PB 97 of 2019) (Special Arrangement) to remove a brand of naloxone, Nyxoid (UK), that can be supplied under the Take Home Naloxone program as an alternative brand.

Background

The Take Home Naloxone program, established by the Special Arrangement, enables the supply of naloxone on the Pharmaceutical Benefits Scheme (PBS) for persons who are at risk of an opioid overdose and persons who are likely to be able to assist such persons, outside of the normal PBS arrangements.

The Special Arrangement enables the supplies of naloxone, free of charge to patients and without a prescription, by hospitals, pharmacists, certain medical practitioners, and other authorised persons or organisations such as needle and syringe programs, alcohol drug treatment centres or correctional release programs.

Medicines able to be supplied under the Take Home Naloxone program (designated pharmaceutical benefits) are set out in Schedule 1 of the Special Arrangement. Each designated pharmaceutical benefit is a brand of a naloxone drug in a specified form and with a specified manner of administration.

The Instrument removes the following pharmaceutical benefit from Schedule 1 of the Special Arrangement:

- Nyxoid (UK) – Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2.

The Therapeutic Goods Administration (TGA) approved the temporary importation and supply of Nyxoid (UK) nasal spray solution under subsection 19A(1) of the *Therapeutic Goods Act 1989* (Therapeutic Goods Act) due to the reported shortage of Nyxoid nasal spray. The Pharmaceutical Benefits Advisory Committee (PBAC) recommended Nyxoid (UK) be temporarily listed on the PBS for the duration of the approval under subsection 19A(1) of the Therapeutic Goods Act to enable continued access to a nasal spray formulation throughout the shortage period. Nyxoid (UK) was then listed on the PBS and subsequently included in the Take Home Naloxone program through *National Health (Take Home Naloxone) Amendment (2023 Measures No.2) Special Arrangement 2023 (PB 101 of 2023)*.

The Nyxoid nasal spray is no longer in shortage and consequently the approval under subsection 19A(1) of the *Therapeutic Goods Act 1989* to supply Nyxoid (UK) is no longer in force. Nyxoid (UK) will no longer be available for distribution and supply in Australia and individuals will continue to have access to a naloxone nasal spray with the Nyxoid formulation. Nyxoid (UK) will subsequently be removed from the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*, which instructs the medicines which can be listed on the PBS. Nyxoid (UK) will subsequently be removed from the Take Home Naloxone program and Schedule 1 of the Special Arrangement.

Authority

Subsection 100(1) of the *National Health Act 1953* (Act) enables the Minister to make special arrangements for the supply of certain pharmaceutical benefits to persons who are living in isolated areas; persons who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1) of the Act.

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect subject to a special arrangement made under subsection 100(1).

Commencement

The Instrument commences on 1 November 2024.

Consultation

Advice was sought from the PBAC on the selection of brands, forms and strengths of naloxone for inclusion in the Special Arrangement as originally made.

The PBAC is an independent expert body established by section 100A of the Act, which makes recommendations to the Minister for Health and Aged Care about which drugs and medicinal preparations should be available as pharmaceutical benefits and the circumstances in which they should be available.

The removal of Nyxoid (UK) is required as the formulation will be removed from the PBS and will no longer be available for distribution and supply in Australia. No additional consultation with the sponsor was considered necessary.

Consultation with the TGA took place to confirm the expiration of the subsection 19A(1) approval for Nyxoid (UK). Consultation was sought with Australian Healthcare Associates who administer payments for the Take Home Naloxone program. Consultation with Services Australia did not take place because they have no administrative function with the Take Home Naloxone program.

Consultation was undertaken with state and territory health departments to advise them of the removal of Nyxoid (UK) from the PBS and Take Home Naloxone program following the shortage of Nyxoid being resolved.

General

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

Details of this instrument are set out in **Attachment A**.

This instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

Details of the National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024 (PB 110 of 2024)

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024* (Instrument) and it may also be cited as PB 110 of 2024.

Section 2 – Commencement

Section 2 provides that the Instrument commences on 1 November 2024.

Section 3 – Authority

Section 3 provides that the Instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 – Schedule

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in applicable items in the Schedule concerned, and that any other item in a Schedule has effect according to its terms. Schedule 1 to the Instrument amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (Special Arrangement).

Schedule 1 – Amendments

Item 1 – Clause 1 of Schedule 1 (table item 5)

The table in Schedule 1 of the Special Arrangement sets out the pharmaceutical benefits that can be supplied under the Take Home Naloxone program. It also specifies the maximum quantity or number of units of the benefit that can be prescribed for supply on the one occasion for the purposes of the program.

Item 1 amends the table in Schedule 1 to the Special Arrangement by removing item 5 that specifies a pharmaceutical benefit, being the Nyxoid (UK) brand of the pharmaceutical item that is the drug naloxone, nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2, with the manner of nasal administration. The Nyxoid (UK) brand was separately repealed as a pharmaceutical benefit for the purposes of the PBS on 1 November 2024 under the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024*.

ATTACHMENT B

Statement of Compatibility with Human Rights

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

National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024

PB 110 of 2024

This 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 Instrument

The *National Health (Take Home Naloxone) Amendment (2024 Measures No. 1) Special Arrangement 2024* (PB 110 of 2024) (Instrument) amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (PB 97 of 2019) (Special Arrangement) to remove a new brand of naloxone, Nyxoid (UK), from the list of designated pharmaceutical benefits contained in Schedule 1 of the Special Arrangement, which can be supplied under the Take Home Naloxone program as an alternative brand.

The Special Arrangement provides for the supply, under the Pharmaceutical Benefits Scheme (PBS), of naloxone for persons who are risk of an opioid overdose and persons who are likely to be able to assist such persons, outside normal PBS arrangements.

The Special Arrangement enables the supplies of naloxone, free of charge to patients and without a prescription, by hospitals, pharmacists, certain medical practitioners, and other authorised persons or organisations such as needle and syringe programs, alcohol drug treatment centres or correctional release programs.

Human rights implications

The Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with 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 Instrument also engages Article 9 of the ICESCR by ensuring access to a social security scheme to all persons, enabling access to essential health care and promoting social inclusion.

The PBS is a benefit scheme which assists with the advancement of this human right by providing for subsidised access to medicines by patients. The role of the Pharmaceutical Benefits Advisory Committee in making recommendations and providing advice about benefits that should be included on the PBS ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

This Instrument assists with the advancement of the rights to health and social security by ensuring continued access to PBS medicines, at no cost, for the treatment of acute opioid overdose. This Instrument will provide continued access for treatment options under the Take Home Naloxone program. The Nyxoid (UK) brand of naloxone is not included in the Australian Register of Therapeutic Goods and was only temporarily available for supply in Australia under special approval from the Therapeutic Goods Administration. The shortage of the Nyxoid nasal spray has resolved and patients will continue to have access to a nasal spray formulation.

Conclusion

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

Sarah Norris
Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health and Aged Care