EXPLANATORY STATEMENT

National Health Act 1953

National Health (Take Home Naloxone) Amendment (2023 Measures No. 2) Special Arrangement 2023

PB 101 of 2023

Purpose and operation

The *National Health (Take Home Naloxone) Amendment (2023 Measures No. 2) Special Arrangement 2023* (PB 101 of 2023) (Instrument) amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (PB 97 of 2019) (Special Arrangement) to include a new brand of naloxone, Nyxoid (UK), that can be supplied under the Take Home Naloxone program as an alternative brand while there continues to be shortages of other naloxone nasal sprays in Australia.

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 inserts the following pharmaceutical benefit into Schedule 1 of the Special Arrangement:

- Nyxoid (UK) – Nasal spray containing naloxone 1.8mg nasal spray solution in a single-dose container

The Special Arrangement will also specify that the maximum quantity of Nyxoid (UK) that can be supplied to a designated person (being a person who is at risk of an opioid overdose or who is likely to be able to assist such a person) is 4 nasal sprays (2 packs of 2 sprays).

The Nyxoid brand of 1.8mg naloxone nasal spray solution is a designated pharmaceutical benefit on the Take Home Naloxone program that is currently listed in Schedule 1 of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PBS Listing Instrument) and Schedule 1 of the Special Arrangement. The sponsor for Nyxoid has reported a temporary medicine shortage to the Therapeutic Goods Administration (TGA). Nyxoid is the only nasal spray formulation on the Australian Register of Therapeutic Goods (ARTG), which is a register of therapeutic goods available for importation and supply in Australia. The 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.

Although the ARTG and TGA shortage information refers to Nyxoid as containing 2.2mg of naloxone hydrochloride dihydrate, rather than 1.8mg of naloxone as the PBS product is described, this is simply the result of a 2020 update to the ARTG Product Information. The forms of the Nyxoid and Nyxoid (UK) products are equivalent, and both contain equal amounts of naloxone.

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.

It is intended that Nyxoid (UK) will only be available for supply under the Special Arrangement 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. Once the Nyxoid shortage is resolved and its approval of supply under subsection 19A(1) of the Therapeutic Goods Act is no longer in force, Nyxoid (UK) will be removed from the PBS Listing Instrument and Schedule 1 of the Special Arrangement as the TGA approved nasal spray will be available to access through the Take Home Naloxone program.

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 October 2023.

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 addition of Nyxoid (UK) is at the request of the responsible person, which is an additional brand of a pharmaceutical item that is already included under the Take Home Naloxone program. No additional consultation with the sponsor was considered necessary.

Consultation with the TGA took place to understand the market situation across the naloxone brands. 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 understand the requirement for Nyxoid (UK) to be temporarily available on the Take Home Naloxone program while Nyxoid is undergoing supply issues. The preference for a nasal spray was noted due to ease of administration and providing product education.

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 (2023 Measures No. 2) Special Arrangement 2023 (PB 101 of 2023)

Section 1 – Name

Section 1 provides that the name of the instrument is the *National Health (Take Home Naloxone) Amendment (2023 Measures No. 2) Special Arrangement 2023* (Instrument) and it may also be cited as PB 101 of 2023.

Section 2 – Commencement

Section 2 provides that the Instrument commences on 1 October 2023.

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 (after table item 4)

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.

Clause 1 amends the table in Schedule 1 to the Special Arrangement by inserting a new item 5 that specifies a new pharmaceutical benefit, being the Nyxoid (UK) brand of the pharmaceutical item that is the drug naloxone, in the form of nasal spray containing naloxone hydrochloride 1.8 milligrams in 0.1 mL single dose unit (2 units), with the manner of nasal administration. It also specifies a maximum quantity or number of units that can be prescribed for supply on one occasion of 2 (being 2 lots of 2 single dose units). The Nyxoid (UK) brand was separately determined as a pharmaceutical benefit for the purposes of the PBS on 1 September 2023 under the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*.

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 (2023 Measures No. 2) Special Arrangement 2023

PB 101 of 2023

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 (2023 Measures No. 2) Special Arrangement 2023* (PB 101 of 2023) (Instrument) amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (PB 97 of 2019) (Special Arrangement) to include a new brand of naloxone, Nyxoid (UK), to 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 while there continues to be shortages of other naloxone nasal sprays in Australia.

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 Pharmaceutical Benefits Scheme (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 and increase availability of treatment in response to the shortage of supply of the only form of naloxone that can be administered as a nasal spray under the Take Home Naloxone program. The Nyxoid (UK) brand of naloxone is not included in the Australian Register of Therapeutic Goods and is only temporarily available for supply in Australia under special approval from the Therapeutic Goods Administration. It is intended that once the other naloxone nasal spray available under the Take Home Naloxone program ceases to be in shortage, the Nyxoid (UK) brand will cease to be available under the program.

Conclusion

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

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