

## EXPLANATORY STATEMENT

### *National Health Act 1953*

### *National Health (Take Home Naloxone) Amendment (2023 Measures No. 1) Special Arrangement 2023*

### **PB 73 of 2023**

#### **Purpose and operation**

The *National Health (Take Home Naloxone) Amendment (2023 Measures No. 1) Special Arrangement 2023* (PB 73 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 that can be supplied under the Take Home Naloxone program.

#### **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:

- Naloxone – Injection containing naloxone hydrochloride 400 microgram in 1 mL ampoule – Injection – NALOXONE SXP

The Special Arrangement will also specify that the maximum quantity of NALOXONE SXP 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 10 ampoules.

NALOXONE SXP is already listed on the PBS for general supply (section 85 supply). The Instrument merely enables it to be supplied under the Special Arrangement.

#### **Authority**

Subsection 100(1) of the *National Health Act 1953* (the 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 August 2023.

## **Consultation**

Advice was sought from the Pharmaceutical Benefits Advisory Committee (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 about which drugs and medicinal preparations should be available as pharmaceutical benefits and the circumstances in which they should be available.

The addition of NALOXONE SXP is at the request of the responsible person, which is an additional brand of a pharmaceutical item which is already included under the Take Home Naloxone Program. No additional consultation with the sponsor was considered necessary.

Consultation with the Therapeutic Goods Administration (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.

## **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. 1) Special Arrangement 2023 (PB 73 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. 1) Special Arrangement 2023* (Instrument) and it may also be cited as PB 73 of 2023.

**Section 2 - Commencement**

Section 2 provides that the Instrument commences on 1 August 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 2)**

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 2A that specified a new pharmaceutical benefit, being the NALOXONE SXP brand of the pharmaceutical item that is the drug naloxone, in the form Injection containing naloxone hydrochloride 400 micrograms in 1 mL ampoule, with the manner of administration via injection. It also specifies a maximum quantity or number of units of 10 ampoules.

**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. 1) Special Arrangement 2023***

**PB 73 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. 1) Special Arrangement 2023* (PB 73 of 2023) (Instrument) amends the *National Health (Take Home Naloxone) Special Arrangement 2019* (PB 97 of 2019) (Special Arrangement). 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.

The Instrument is made under subsection 100(2) of the *National Health Act 1953* and adds a new brand of pharmaceutical benefit with the drug naloxone to the list of designated pharmaceutical benefits contained in Schedule 1 of the Special Arrangement. Designated pharmaceutical benefits are able to be supplied under the Special Arrangement.

**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 this right by ensuring continued access to PBS medicines, at no cost, for the treatment of acute opioid overdose. This Instrument will provide more patient choice for treatment options and increase availability of treatment in the event of shortage of supply of one brand of pharmaceutical item under the Take Home Naloxone Program.

**Conclusion**

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

**David Laffan**  
**Assistant Secretary**

**Pharmacy Branch  
Technology Assessment and Access Division  
Department of Health and Aged Care**