**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

#### *NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLEGIC PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2022 (No. 1)*

#### PB 72 of 2022

**Purpose**

This is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2022 (No. 1)* (this Instrument). The purpose of this Instrument, made under subsection 100(2) of the Act, is to amend the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* (PB 31 of 2021) (the Special Arrangement) to make changes to the Special Arrangement relating to the Paraplegic and Quadriplegic Program.

The Paraplegic and Quadriplegic Program Special Arrangement provides for ‘authorised associations’ to supply pharmaceutical benefits available under the Special Arrangement to ‘eligible persons’. A person is an ‘eligible person’ for the purposes of the Special Arrangement if they:

1. are an ‘eligible person’ within the meaning of the *Health Insurance Act 1973*, that is, eligible to receive Medicare benefits; and
2. have paraplegia or quadriplegia; and
3. are a member of an ‘authorised association’.

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.

The amendments made by this Instrument include the alteration of responsible person code for a brand of the listed drug bisacodyl listed in Schedule 1 of the Special Arrangement. The amendments also include the addition and deletion of responsible person codes listed in Schedule 2 of the Special Arrangement.

These changes are summarised, by subject matter, in the Attachment.

**Authority**

###### Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

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

###### 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).

**Consultation**

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC).

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

PBAC is an 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 as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations 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. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies were consulted throughout the process of changes to the listings on the PBS. This includes consultation through the PBAC process.

Further consultation for this Instrument was considered unnecessary due to the nature of the consultation that had already taken place.

**General**

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

This instrument commences on 1 August 2022.

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

**ATTACHMENT**

#### PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLEGIC PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2022 (No. 1)*

**Section 1 Name of Instrument**

#### This section provides that the Instrument is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2022 (No. 1)* and may also be cited as PB 72 of 2022.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 August 2022.

**Section 3** **Authority**

This section states that this instrument is made under subsection 100(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 made by this Instrument involve the alteration of responsible person code for a brand of a pharmaceutical benefit listed in Schedule 1 of the Special Arrangement, and the addition and deletion of responsible person codes listed in Schedule 2 of the Special Arrangement. These changes are summarised below.

**SUMMARY OF CHANGES MADE BY THIS INSTRUMENT**

**Alteration of Responsible Person Code**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Responsible Person*** |
| Bisacodyl | Enemas 10 mg in 5 mL, 25 | *Bisalax* | ***From:*** AS | ***To:*** OX |

**Addition of Responsible Person**

|  |
| --- |
| ***Responsible person and code*** |
| Orion Pharma (Aus) Pty Limited (*OX*) |

**Deletion of Responsible Person**

|  |
| --- |
| ***Responsible person and code*** |
| Aspen Pharmacare Australia Pty Limited (*AS*) |

**Statement of Compatibility with Human Rights**

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

***National Health (Paraplegic and Quadriplegic Program) Special Arrangement***

***Amendment Instrument 2022 (No. 1)***

**(PB 72 of 2022)**

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 purpose of this legislative instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021* (PB 31 of 2021) (the Special Arrangement) to make changes to the special arrangement relating to the Paraplegic and Quadriplegic Program.

The Paraplegic and Quadriplegic Program Special Arrangement provides for ‘authorised associations’ to supply pharmaceutical benefits available under the Special Arrangement to ‘eligible persons’ requiring treatment with bowel management medicines. A person is an ‘eligible person’ for the purposes of the Special Arrangement if they:

1. are an ‘eligible person’ within the meaning of the *Health Insurance Act 1973*; and
2. have paraplegia or quadriplegia; and
3. are a member of an ‘authorised association’.

Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument provides for amendments to the Special Arrangement to ensure that the Special Arrangement accurately reflects changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument), made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commences on the same day.

**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 social security and health.

*The Right to Social Security*

The right to social security is contained in Article 9 of the 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 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 UN Committee on Economic Social and Cultural Rights (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 advances the right to health and the right to social security by ensuring that the amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Listing Instrument), that affect the pharmaceutical benefits that may be supplied under the Special Arrangement, are made concurrently.

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

**Conclusion**

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

**Nikolai Tsyganov**

**Assistant Secretary (Acting)**

**Pricing and PBS Policy Branch**

**Technology Assessment and Access Division**

**Department of Health and Aged Care**