**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLEGIC PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2021 (No. 1)***

**PB 66 of 2021**

**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).

**Purpose**

This is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2021 (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’ 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 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 amendment made by this Instrument provides for the deletion of one brand of an existing pharmaceutical item listed in Schedule 1 of the Special Arrangement.

**Consultation**

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 Pharmaceutical Benefits Advisory Committee (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 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 are 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 in the decision to list the medication.

Details of this Instrument are set out in the Attachment.

This Instrument commences on 1 July 2021.

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

**ATTACHMENT**

**PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLEGIC PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2021 (No. 1)***

**Section 1 Name of Instrument**

This section provides the name of this instrument as the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2021 (No. 1)* and may also be cited as PB 66 of 2021.

**Section 2 Commencement**

This section provides that this instrument commences on 1 July 2021.

**Section 3 Amendment of *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2021 (PB 31 of 2021)***

This section provides that Schedule 1 amends the *National Health (**Paraplegic and Quadriplegic Program) Special Arrangement 2021 (PB 31 of 2021)*.

**Schedule Amendments**

The amendment in Schedule 1 involves the deletion of a brand of a pharmaceutical benefit listed in Schedule 1 of the Special Arrangement. This change is summarised below.

**SUMMARY OF CHANGES TO THE PARAPLEGIC AND QUADRIPLEGIC PROGRAM** **MADE BY THIS INSTRUMENT**

**Brand Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125g with electrolytes, 30 (*lax-sachets*) |

**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 2021 (No. 1)***

**(PB 66 of 2021)**

This Special Arrangement 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 Special Arrangement**

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 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 association.

The amendment in Schedule 1 involves the deletion of a brand of a pharmaceutical benefit listed in Schedule 1 of the Special Arrangement.

**Human rights implications**

This Special Arrangement engages the right to equality and non-discrimination contained Article 2(2) of the International Covenant on Economic, Social and Cultural Rights and the right to health contained in Article 12 of that covenant, 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 Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with the advancement of this human right 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 Special Arrangement is compatible with human rights because it promotes the protection of human rights.

**Mariana Crank**

**Assistant Secretary (Acting)**

**Pharmacy Branch**

**Technology Assessment and Access Division**

**Department of Health**