**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

#### *NATIONAL HEALTH (PARAPLEGIC AND QUADRIPLEGIC PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2021 (No. 2)*

#### PB 124 of 2021

**Purpose**

This is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2021 (No. 2)* (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 deletion of a brand of the listed drug
macrogol 3350 for pharmaceutical benefits listed in Schedule 1 of the Special Arrangement. The amendments also include the deletion of the responsible person Amneal Pharmaceuticals Pty Ltd listed in Schedule 2 of the Special Arrangement.

A provision by provision description of this Instrument is contained 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 in the decision to list the medication.

This instrument commences on 1 December 2021.

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 2021 (No. 2)*

**Section 1 Name of Instrument**

#### This section provides that the Instrument is the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement Amendment Instrument 2021 (No. 2)* and may also be cited as PB 124 of 2021.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 December 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 1 Amendments**

The amendments made by this Instrument include the deletion of a brand of a listed drug for pharmaceutical benefits listed in Schedule 1 of the Special Arrangement. The amendments also include the deletion of a responsible person listed in Schedule 2 of the Special Arrangement. These changes are summarised below.

**SUMMARY OF CHANGES**

**Brand Deleted**

|  |  |
| --- | --- |
| ***Listed drug*** | ***Form and brand*** |
| Macrogol 3350 | Sachets containing powder for oral solution 13.125g with electrolytes, 30 (*LaxaCon*) |

**Deletion of Responsible Person**

|  |
| --- |
| ***Responsible person and code*** |
| Amneal Pharmaceuticals Pty Ltd (*EA*) |

**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 2021 (No. 2)***

**(PB 124 of 2021)**

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.

**Human rights implications**

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 PBS is a benefit scheme which assists with 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. The pharmaceutical industry now has a nominee on the PBAC membership.

**Whether there is any detriment to patients by the deletion of these drugs, and if so, how this is compatible with the right to social security**

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Sponsors are private entities that make their own decisions regarding their products and cannot be compelled by the Government to continue to list a product on the PBS. If there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. However, if the final brand of a form of a drug is delisted, this delisting will be considered by PBAC.

**Conclusion**

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

**David Laffan**

**Assistant Secretary**

**Pharmacy Branch**

**Technology Assessment and Access Division**

**Department of Health**