EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Botulinum Toxin Program) Special Arrangement Amendment Instrument 2015 (No.1)

PB 33 of 2015

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

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the Act, is to amend the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011) (the Special Arrangement), to make changes relating to the Botulinum Toxin Program.

The purpose of the Special Arrangement is to allow for botulinum toxin to be supplied to specific patients through eligible medical practitioners.

This instrument:

- Provides that Hospital Medication Chart prescribing, dispensing and claiming regulations contained within the *National Health (Pharmaceutical Benefits) Regulations 1960*, as amended by the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*, do not apply under the Special Arrangement; and
- Clarifies the maximum number of treatment periods of botulinum toxin pharmaceutical benefits an eligible patient is eligible to receive for treatment of moderate to severe spasticity of the upper limbs in adults following a stroke, and defines under what circumstances an eligible patient is considered not to have responded to treatment; and
- Inserts one new listed drug and, consequently, inserts one new responsible person and two new sub-treatment conditions, amends one treatment condition to include an additional listed drug, and inserts arrangements for eligible medical practitioners to hold emergency supplies of the new listed drug; and
- Amends some minor typographical errors.

Consultation

The addition of these amendments was made having regard to advice provided by 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 has broad representation with members appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists; at least one member is 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 are consulted throughout the process for additions and changes to listings on the PBS and for this Special Arrangement. This includes consultation through the PBAC process, which provides for consumers making submissions to the Committee in respect of proposals to be discussed, and agreement to final listing details.

General

This instrument commences on 1 April 2015.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (BOTULINUM TOXIN PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2015 (No. 1)

Section 1 Name of Instrument

This section provides that this instrument is the *National Health (Botulinum Toxin Program) Special Arrangement Amendment Instrument 2015 (No. 1)* and that it may also be cited as PB 33 of 2015.

Section 2 Commencement

This section provides that this instrument commences on 1 April 2015.

Section 3 Amendments to PB 89 of 2011

This section provides that Schedule 1 amends the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011) (the Special Arrangement).

Schedule 1

Item 1 inserts additional regulations to the list of regulations from the *National Health (Pharmaceutical Benefits) Regulations 1960* (The Regulations) detailed at subsection 8(2) of the Special Arrangement that do not apply to the supply of botulinum toxin pharmaceutical benefits under the Special Arrangement, to provide that Hospital Medication Chart prescribing, dispensing and claiming regulations scheduled to commence on 1 April 2015 (as amended by the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015)* do not apply under the Special Arrangement.

Item 2 inserts a new subsection, 11(2), to the Special Arrangement, to clarify the maximum number of treatment periods of botulinum toxin pharmaceutical benefits an eligible patient is eligible to receive for treatment of moderate to severe spasticity of the upper limbs in adults following a stroke. That is, 4 in total per upper limb per lifetime, not 4 per listed drug per upper limb per lifetime.

Item 3 makes an amendment to the subsection of the Special Arrangement lately numbered 11(2), to provide that under the Special Arrangement an eligible patient is not eligible to receive botulinum toxin pharmaceutical benefits for treatment of moderate to severe spasticity of the upper limbs in adults following stroke if the person has already received the maximum number of treatments detailed in the new subsection 11(2) (see item 2 description).

Item 4 amends the subsection of the Special Arrangement lately numbered 11(4)(a), to clarify the maximum number of treatment periods of botulinum toxin pharmaceutical benefits an eligible patient is eligible to receive without responding, for treatment of moderate to severe spasticity of the upper limbs in adults following a stroke. That is, 2 in total per upper limb, not 2 per listed drug per upper limb.

Items 5 and 6 amend subsection 11(4)(b)(ii) of the Special Arrangement to reflect the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description). Specifically, the amendment provides that an eligible patient is not eligible to receive botulinum toxin pharmaceutical benefits for treatment of moderate to severe spasticity of the upper limbs in adults following stroke if the eligible patient demonstrates a known sensitivity to any of the listed drugs, including the new listed drug.

Item 7 inserts a new subsection, 11(7), into the Special Arrangement. The new subsection defines the circumstances under which an eligible patient receiving botulinum toxin pharmaceutical benefits for treatment of moderate to severe spasticity of the upper limbs in adults following a stroke is considered to have not responded to treatment. That is, when the eligible patient has not had a decrease in spasticity rating of greater than 1, using the modified Ashworth Scale, in at least one joint.

Items 8, 9, 10 and 11 make consequential amendments to the subsection numbering in section 11 of the Special Arrangement, to reflect the insertion of the new subsection 11(2) (see item 2 description).

Items 12, 13 and 14 make minor typographical amendments to subsection 12B(1)(c) and section 17B of the Special Arrangement. In subsection 12B(1)(c) the word 'phrophylatic' is replaced with 'prophylactic' and the word 'migrane' is replaced with 'migraine'. In section 17B the word 'overctive' in the section title is replaced with 'overactive'.

Items 15 and 16 make consequential amendments to subsections 18(4)(b)(ii) and 18(5)(b)(ii) of the Special Arrangement, to reflect the insertion of a new sub-treatment condition (1B) into Schedule 3 of the Special Arrangement (see item 25 description). Specifically, the amendments allow for applicant practitioners who are specialists in ophthalmology (subsection 18(4)(b)(ii)), or neurology, otolaryngology head and neck surgery, or plastic surgery (subsection 18(5)(b)(ii)) to provide evidence of their training, for the purposes of seeking authorisation to administer botulinum toxin benefits for the new sub-treatment condition (1B), in the form of a letter from the responsible person for a botulinum toxin pharmaceutical benefit that has the same listed drug as is listed in the column in Schedule 3 headed 'Listed Drug in Relevant Pharmaceutical Benefit' for the new sub-treatment condition (1B).

Item 17 inserts a new subsection into the Special Arrangement, 26(5), consequential to the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description), allowing eligible medical practitioners to hold emergency supplies of the new listed drug.

Items 18, 19, 20, 21 and 22 make consequential amendments to the subsection numbering in section 26 of the Special Arrangement, to reflect the insertion of the new subsection 26(5) (see item 17 description).

Item 23 inserts a new listed drug into Schedule 1 of the Special Arrangement.

Item 24 inserts a new responsible person into Schedule 2 of the Special Arrangement, consequential to the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description).

Item 25 inserts a new sub-treatment category into Schedule 3 of the Special Arrangement, treatment of blepharospasm in an adult (1B), consequential to the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description).

Item 26 inserts a new sub-treatment category into Schedule 3 of the Special Arrangement, treatment of spasmodic torticollis in an adult, either as monotherapy or as adjunctive therapy to current standard care (4A), consequential to the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description).

Item 27 inserts a new listed drug into the column titled 'Listed Drug in Relevant Pharmaceutical Benefit' for treatment category 7 (treatment of moderate to severe spasticity of the upper limbs in adults following stroke, as second line therapy when standard management has failed or as an adjunct to physical therapy) in Schedule 3 of the Special Arrangement, consequential to the insertion of a new listed drug into Schedule 1 of the Special Arrangement (see item 23 description).

Statement of Compatibility with Human Rights

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

National Health (Botulinum Toxin Program) Special Arrangement Amendment Instrument 2015 (No. 1)

This legislative 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 Legislative Instrument

The purpose of this legislative instrument, made under subsections 100(1) and (2) of the *National Health Act 1953*, is to amend the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011) (the Special Arrangement) to make changes relating to the Botulinum Toxin Program.

The purpose of the Special Arrangement is to allow for botulinum toxin to be supplied to specific patients through eligible medical practitioners.

This instrument:

- Provides that medication chart prescriptions regulations contained within the *National Health (Pharmaceutical Benefits) Regulations 1960*, as amended by the *National Health (Pharmaceutical Benefits) Amendment (Medication Chart Prescriptions) Regulation 2015*, do not apply under the Special Arrangement; and
- Clarifies the maximum number of treatment periods of botulinum toxin pharmaceutical benefits an eligible patient is eligible to receive for treatment of moderate to severe spasticity of the upper limbs in adults following a stroke, and defines under what circumstances an eligible patient is considered not to have responded to treatment; and
- Inserts one new listed drug and, consequently, inserts one new responsible person and two new sub-treatment conditions, amends one treatment condition to include an additional listed drug, and inserts arrangements for eligible medical practitioners to hold emergency supplies of the new listed drug; and
- Amends some minor typographical errors.

Human rights implications

This legislative instrument engages Article 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 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.

Conclusion

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

Kim Bessell
Assistant Secretary
Pharmaceutical Access Branch
Principal Pharmaceutical Advisor
Pharmaceutical Benefits Division
Department of Health