EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 8)

PB 77 of 2012

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 (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement), to make changes to the special arrangement relating to the efficient funding of chemotherapy.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines ("chemotherapy pharmaceutical benefits") to eligible patients being treated for cancer, to reflect the 2010 budget measure titled 'Revised arrangements for the efficient funding of chemotherapy drugs'. This Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment ("related pharmaceutical benefits") at certain public hospitals.

This instrument makes changes to the pharmaceutical benefits available under the section 100 special arrangement for the efficient funding of chemotherapy. These changes reflect changes made by the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the main listing instrument) made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commence on the same day.

This Instrument:

- adds a new pharmaceutical benefit, circumstances and purposes for the listed drug 'Bortezomib';
- amends the maximum quantity and number of repeats for 3 pharmaceutical benefits with the listed drug 'Folinic acid' and;
- removes 9 listed brands with the listed drugs 'Etoposide', 'Gemcitabine', 'Irinotecan', 'Ondansetron' and 'Oxaliplatin';

Consultations

An ongoing and formal process of consultation in relation to matters relevant to this instrument 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 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.

This Instrument commences on 1 October 2012.

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

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 8)

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 8)* and that it may also be cited as PB 77 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 October 2012.

Section 3 Amendments to PB 79 of 2011

This section provides that Schedule 1 amends the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011) (the Special Arrangement).

Schedule 1

Item 1 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Bortezomib' by adding a pharmaceutical benefit in the form 'Powder for injection 1mg' with manner of administration 'Injection' and brand 'Velcade'.

Item 2 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Etoposide' by removing a pharmaceutical benefit in the form 'Solution for I.V. infusion 100 mg in 5 mL vial' with manner of administration 'Injection' and brand 'Hospira Pty Limited'.

Item 3 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Gemcitabine' by removing a pharmaceutical benefit in the form 'Powder for I.V. infusion 1g (as hydrochloride)' with manner of administration 'Injection' and brand 'Gemcite'.

Item 4 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Gemcitabine' by removing a pharmaceutical benefit in the form 'Powder for I.V. infusion 200mg (as hydrochloride)' with manner of administration 'Injection' and brand 'Gemcite'.

Item 5 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Irinotecan' by removing a pharmaceutical benefit in the form 'I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL' with manner of administration 'Injection' and brand 'Camptosar'.

Item 6 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Oxaliplatin' by removing a pharmaceutical benefit in the form **'**Powder for I.V. infusion 100mg' with manner of administration 'Injection' and brand 'Oxalatin'.

Item 7 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Oxaliplatin' by removing a pharmaceutical benefit in the form **'**Powder for I.V. infusion 100mg' with manner of administration 'Injection' and brand 'Oxaliplatin Link'.

Item 8 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Oxaliplatin' by removing a pharmaceutical benefit in the form **'**Powder for I.V. infusion 50mg' with manner of administration 'Injection' and brand 'Oxalatin'.

Item 9 amends the entry in Schedule 1 Part 1 of the Special Arrangement for 'Oxaliplatin' by removing a pharmaceutical benefit in the form **'**Powder for I.V. infusion 50mg' with manner of administration 'Injection' and brand 'Oxaliplatin Link'.

Item 10 amends the entry in Schedule 1 Part 2 of the Special Arrangement by adding the maximum amount and number of repeats for the purposes associated with the new pharmaceutical benefit with the listed drug 'Bortezomib'.

Item 11 amends the entry in Schedule 2 of the Special Arrangement by changing the maximum amount and number of repeats for pharmaceutical benefits with the listed drug 'Folinic acid' in the form 'Injection containing calcium folinate equivalent to 50mg folinic acid in 5ml'.

Item 12 amends the entry in Schedule 2 of the Special Arrangement for 'Ondansetron' by removing a pharmaceutical benefit in the form 'Tablet 4 mg (as hydrochloride dihydrate)' with manner of administration 'Oral' and brand 'Zondan'.

Item 13 amends the entry in Schedule 2 of the Special Arrangement for 'Ondansetron' by removing a pharmaceutical benefit in the form 'Tablet 8 mg (as hydrochloride dihydrate)' with manner of administration 'Oral' and brand 'Zondan'.

Item 14 amends the entry Schedule 4 of the Special Arrangement by adding circumstances codes, purposes codes and associated circumstances and purposes for the new pharmaceutical benefit with the listed drug 'Bortezomib'.

Statement of Compatibility with Human Rights

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

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2012 (No. 8)

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

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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 Pharmaceutical Benefits Scheme (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.

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