EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health and Ageing

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2011 (No. 1)

PB 100 of 2011

Purpose

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the *National Health Act 1953* (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.

Section 100 special arrangements and Part VII of the Act

Subsection 100(1) enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

(a) who are living in isolated areas: or
(b) who are receiving treatment in circumstances in which generally available pharmaceutical benefits are inadequate for that treatment; or
(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(3) provides that Part VII of the Act, and regulations and other legislative instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

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

Changes to the Special Arrangement made by this Instrument

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

This Instrument:

- Adds 8 pharmaceutical benefits with the listed drugs 'Carboplatin', 'Gemcitabine', 'Irinotecan' and 'Paclitaxel';

- Changes circumstances for pharmaceutical benefits with the listed drugs ‘Docetaxel’, ‘Paclitaxel’ and ‘Paclitaxel, nanoparticle albumin-bound’; and
- Changes purposes for pharmaceutical benefits with the listed drug ‘Docetaxel’.

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.

General

This Instrument commences on 1 January 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 2011 (No. 1)*

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2011 (No. 1)* and that it may also be cited as PB 100 of 2011.

Section 2 Commencement

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

Section 3 Amendments to PB 79 of 2010

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

Schedule 1

Item 1 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Carboplatin' by adding a new pharmaceutical benefit, which is the listed drug 'Carboplatin' in the form 'Solution for I.V. injection 450 mg in 45 mL' with manner of administration 'Injection' and brand 'Carboplatin Kabi'.

Item 2 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL with solvent' by removing circumstances code 'C3893' and inserting circumstances code 'C3955' and removing circumstances code 'C3918' and inserting circumstances code 'C3956'.

Item 3 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent' by removing circumstances code 'C3893' and inserting circumstances code 'C3955' and removing circumstances code 'C3918' and inserting circumstances code 'C3956'.

Item 4 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Powder for I.V. infusion 20 mg with solvent' by removing circumstances code 'C3893' and inserting circumstances code 'C3955'.

Item 5 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Powder for I.V. infusion 80 mg with solvent' by removing circumstances code 'C3893' and inserting circumstances code 'C3955'.

Item 6 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Solution concentrate for I.V. infusion 140 mg in 7 ml' by removing circumstances code 'C3893' and inserting circumstances code 'C3955'and removing circumstances code 'C3918' and inserting circumstances code 'C3956'.

Item 7 amends the entry in Schedule 1 Part 1 of the Principal Instrument for 'Docetaxel' in the form 'Solution concentrate for I.V. infusion 160 mg in 16 ml' by removing circumstances

code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 8 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 20 mg in 1 ml’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 9 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 20 mg in 2 ml’ with manner of administration ‘Injection’ and brand ‘DBL Docetaxel Concentrated Injection’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 10 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 20 mg in 2 mL’ with manner of administration ‘Injection’ and brand ‘Docetaxel Ebewe’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’.

Item 11 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 20 mg in 2 ml’ with manner of administration ‘Injection’ and brand ‘Docetaxel Sandoz’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 12 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 80 mg in 4 ml’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 13 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 80 mg in 8 ml’ with manner of administration ‘Injection’ and brand ‘DBL Docetaxel Concentrated Injection’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 14 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 80 mg in 8 mL’ with manner of administration ‘Injection’ and brand ‘Docetaxel Ebewe’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’.

Item 15 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Docetaxel’ in the form ‘Solution concentrate for I.V. infusion 80 mg in 8 ml’ with manner of administration ‘Injection’ and brand ‘Docetaxel Sandoz’ by removing circumstances code ‘C3893’ and inserting circumstances code ‘C3955’and removing circumstances code ‘C3918’ and inserting circumstances code ‘C3956’.

Item 16 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Gemcitabine’ by adding 3 pharmaceutical benefits, which are the listed drug ‘Gemcitabine’

- in the form ‘Solution for injection 200 mg (as hydrochloride) in 5.3 mL’ with manner of administration ‘Injection’ and brand ‘DBL Gemcitabine Injection’,
- in the form ‘Solution for injection 1 g (as hydrochloride) in 26.3 mL’ with manner of administration ‘Injection’ and brand ‘DBL Gemcitabine Injection’,

- in the form ‘Solution for injection 2 g (as hydrochloride) in 52.6 mL’ with manner of administration ‘Injection’ and brand ‘DBL Gemcitabine Injection’.

Item 17 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Irinotecan’ by adding a pharmaceutical benefit, which is the listed drug ‘Irinotecan’ in the form ‘I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL’ with manner of administration ‘Injection’ and brand ‘Tecan’.

Item 18 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Paclitaxel’ by removing circumstances codes ‘C3893’ and ‘C3918’ and inserting circumstances codes ‘C3955’ and ‘C3956’.

Item 19 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Paclitaxel’ by adding a pharmaceutical benefit, which is the listed drug ‘Paclitaxel’ in the form ‘Solution concentrate for I.V. infusion 100 mg in 16.7 mL’ with manner of administration ‘Injection’ and brand ‘Paclitaxel Pfizer’.

Item 20 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Paclitaxel’ by adding a pharmaceutical benefit, which is the listed drug ‘Paclitaxel’ in the form ‘Solution concentrate for I.V. infusion 30 mg in 5 mL’ with manner of administration ‘Injection’ and brand ‘Paclitaxel Pfizer’.

Item 21 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Paclitaxel’ by adding a pharmaceutical benefit, which is the listed drug ‘Paclitaxel’ in the form ‘Solution concentrate for I.V. infusion 300 mg in 50 mL’ with manner of administration ‘Injection’ and brand ‘Paclitaxel Pfizer’.

Item 22 amends the entry in Schedule 1 Part 1 of the Principal Instrument for ‘Paclitaxel, nanoparticle albumin-bound’ by removing circumstances code ‘C3897’ and inserting circumstances codes ‘C3955’ and ‘C3956’.

Item 23 amends the entry in Schedule 4 of the Principal Instrument for ‘Docetaxel’ by removing circumstances codes ‘C3893’ and ‘C3918’ and the circumstances associated with them and inserting circumstances codes ‘C3955’ and ‘C3956’ and the circumstances associated with them.

Item 24 amends the entry in Schedule 4 of the Principal Instrument for ‘Paclitaxel’ by removing circumstances codes ‘C3893’ and ‘C3918’ and the circumstances associated with them and inserting circumstances codes ‘C3955’ and ‘C3956’ and the circumstances associated with them.

Item 25 amends the entry in Schedule 4 of the Principal Instrument for ‘Paclitaxel, nanoparticle albumin-bound’ by removing circumstances code ‘C3897’ and the circumstances associated with it and inserting circumstances codes ‘C3955’ and ‘C3956’ and the circumstances associated with them.