EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2020 (No. 6)

PB 60 of 2020

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 Instrument, made under subsection 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 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'. The 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 amendments to the Special Arrangement to reflect changes made 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.

Schedule 1 to this Instrument provides for amendment of the definitions for 'diluent fee', 'dispensing fee', 'distribution fee' and 'preparation fee' to reflect the re-basing of these fees for 1 July 2020. It also provides for the deletion of two forms of the listed drug ondansetron, the alteration of circumstances in which a prescription may be written for the supply of the listed drugs atezolizumab, brentuximab vedotin and trastuzumab emtansine, and the deletion of seven brands of existing pharmaceutical items. These changes are summarised, by subject matter, in the Attachment.

Consultations

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). The 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. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia and its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

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 these interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

Pharmaceutical companies are consulted throughout the process for additions and changes to listings on the Pharmaceutical Benefits Scheme (PBS), including consultation through the PBAC process and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that has already taken place.

This Instrument commences on 1 July 2020.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2020 (No. 6)*

Section 1 Name of Instrument

This section provides the name of this Instrument as the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2020 (No. 6)* and may also be cited as PB 60 of 2020.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2020.

Section 3 Amendment of *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (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).

Schedule 1 Amendments

The amendments in Schedule 1 involve the alteration of definitions for a number of fees, the deletion of forms of a listed drug, the deletion of brands, and alterations to the circumstances for prescribing various pharmaceutical benefits available on the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT 2011* MADE BY THIS INSTRUMENT

Alteration of Fees

Fee Name	***Fee Amount***
Diluent fee	***From:*** $5.35 ***To:*** $5.44
Dispensing fee	***From:*** $7.39 ***To:*** $7.74
Distribution fee	***From:*** $27.02 ***To:*** $27.45
Preparation fee	***From:*** $85.06 ***To:*** $85.78

Forms Deleted

Listed Drug	***Form***
Ondansetron	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL
	I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL

Brands Deleted

Listed Drug	*Form and Brand*
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. (*Bleo 15K*)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL (*IRINOTECAN ACT*)
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL (*IRINOTECAN ACT*)
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL (*Paclitaxel ACT*)
	Solution concentrate for I.V. infusion 100 mg in 16.7 mL (*Paclitaxel ACT*)
	Solution concentrate for I.V. infusion 150 mg in 25 mL (*Paclitaxel ACT*)
	Solution concentrate for I.V. infusion 300 mg in 50 mL (*Paclitaxel ACT*)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Atezolizumab

Brentuximab vedotin

Trastuzumab emtansine

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Trastuzumab emtansine	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status**. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act* 2003. The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).	The WHO/ ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status

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 2020 (No. 6)

(PB 60 of 2020)

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 subsection 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 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'. The 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 provides for amendments to the Special Arrangement to ensure that the Special Arrangement accurately reflects changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commence on the same day.

The amendments in Schedule 1 involve the alteration of definitions for a number of fees, the deletion of forms of a listed drug, the deletion of brands, and alterations to the circumstances for prescribing various pharmaceutical benefits available on the Special Arrangement.

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

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