EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2024 (No. 1)

PB 6 of 2024

Purpose

This is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2024 (No. 1)* (PB 6 of 2024) (this Instrument). The purpose of this 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 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 commences on the same day.

Schedule 1 to this Instrument provides for the addition of the listed drug tebentafusp, the addition of a brand of the listed drug palonosetron, and the deletion of brands of the listed drugs bleomycin, irinotecan, methotrexate, and ondansetron. It also provides for the addition and deletion of responsible person codes for the list of responsible persons and the alteration of circumstances in which a prescription may be written for the listed drugs ipilimumab, nivolumab, and pembrolizumab under the Special Arrangement.

These changes are summarised, by subject matter, in the Attachment.

Authority

Subsection 100(1) of 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).

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

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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.

General

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

This Instrument commences on 1 February 2024.

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

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ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2024 (No. 1)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2024 (No. 1)* and may also be cited as PB 6 of 2024.

Section 2 Commencement

This section provides that this Instrument commences on 1 February 2024.

Section 3 Authority

This section states that this instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of a listed drug, the addition and deletion of brands of listed drugs, the addition and deletion of responsible person codes from the list of responsible persons, and the alteration of circumstances in which a prescription may be written for listed drugs under the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE *EFFICIENT FUNDING OF CHEMOTHERAPY PROGRAM* MADE BY THIS INSTRUMENT

Drug Added

Listed Drug

Tebentafusp

Brand Added

Listed Drug	***Form***
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL *(PALONOSETRON Medsurge)*

Brands Deleted

Listed Drug	***Form***
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. *(CIPLA BLEOMYCIN)*
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL *(MEDITAB IRINOTECAN)*

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	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL *(MEDITAB IRINOTECAN)*
Methotrexate	Solution concentrate for I.V. infusion 1000 mg in 10 mL vial *(Pfizer Australia Pty Ltd)*
Ondansetron	Tablet (orally disintegrating) 4 mg *(Ondansetron AN ODT)*
	Tablet 4 mg (as hydrochloride dihydrate) *(Ondansetron AN)*
	Tablet (orally disintegrating) 8 mg *(Ondansetron AN ODT)*
	Tablet 8 mg (as hydrochloride dihydrate) *(Ondansetron AN)*

Addition of Responsible Persons

Medsurge Healthcare Pty Ltd *(DZ)*

MEDISON PHARMA AUSTRALIA PTY LIMITED *(WM)*

Deletion of Responsible Person

Amneal Pharmaceuticals Pty Ltd *(EA)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Ipilimumab

Nivolumab

Pembrolizumab

Documents Incorporated by Reference

Listed Drug	***Document incorporated***	***Document access***
Tebentafusp	**Approved Product Information/Australian Product Information/TGA-approved Product Information.** 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*. This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Nivolumab Ipilimumab	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.** 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 available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-

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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.).	performance-status

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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 2024 (No. 1)

(PB 6 of 2024)

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* (the Listing Instrument), made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commences on the same day.

Human Rights Implications

This Instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the 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 Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the 'highest attainable standard of health' takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

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Analysis

This Instrument advances the right to health and the right to social security by ensuring that the amendments to the Listing Instrument, that affect the pharmaceutical benefits that may be supplied under the Special Arrangement, are made concurrently. This Instrument provides for the addition of the listed drug tebentafusp, the addition of a brand of the listed drug palonosetron, and the deletion of brands of the listed drugs bleomycin, irinotecan, methotrexate, and ondansetron.

The Listing Instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which assists with advancement of these human rights 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.

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. The deletion of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

Conclusion

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

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