

EXPLANATORY STATEMENT

National Health Act 1953

NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2022 (No. 2)

PB 13 of 2022

Purpose

The purpose of this legislative instrument, made under subsection 89A(3) of the *National Health Act 1953* (the Act), is to amend the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* to make changes to the pharmaceutical benefits eligible to be provided as a Continued Dispensing supply.

The *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (the Principal Instrument) expands the list of pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and provides the conditions for such a supply (a ‘Continued Dispensing’ supply).

The amendments made by this instrument reflect amendments 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.

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply (‘Continued Dispensing’).

This instrument does not override state and territory poisons laws. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to the eligible medicines.

Amendments made by this Instrument

Schedule 1 to this instrument provides for the addition of the listed drug zanubrutinib and for the addition of a form of the listed drugs chorionic gonadotrophin, and etanercept. It also provides for the deletion of forms of the listed drugs cefotaxime, and methotrexate for the list of pharmaceutical benefits that may be supplied as a Continued Dispensing supply. These changes are summarised, by subject matter, in the Attachment.

Consultation

This instrument affects approved pharmacists, at or from premises in respect of which the pharmacist is for the time being approved, supplying a pharmaceutical benefit. Consultation was undertaken prior to commencement of the Principal Instrument with relevant peak bodies including the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia. The Department has also undertaken direct consultation with Services Australia and has consulted with state and territory Departments of Health about implementation.

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

General

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

This instrument commences on 1 March 2022.

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

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (CONTINUED DISPENSING – EMERGENCY MEASURES) AMENDMENT DETERMINATION 2022 (No. 2)

Section 1 Name

This section provides that the Instrument is the *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2022 (No. 2)* and may also be cited as PB 13 of 2022.

Section 2 Commencement

This section provides that the Instrument commences on 1 March 2022.

Section 3 Authority

This section states that this Instrument is made under subsection 89A(3) of the 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, and the addition and deletion of forms of listed drugs for the list of pharmaceutical benefits that can be supplied as a Continued Dispensing supply. These changes are summarised below.

SUMMARY OF CHANGES TO THE CONTINUED DISPENSING – EMERGENCY MEASURE MADE BY THIS INSTRUMENT

Listed Drugs Added

Listed Drug

Zanubrutinib

Forms Added

Listed Drug

Form

Chorionic gonadotrophin

Injection set containing powder for injection 1,500 units, 3 and solvent 1 mL, 3 (s19A)

Etanercept

Injection 50 mg in 1 mL single use dose-dispenser cartridges, 4

Forms Deleted

Listed Drug

Form

Cefotaxime

Powder for injection 2 g (as sodium)

Methotrexate

Injection 7.5 mg in 0.3 mL pre-filled syringe

Injection 10 mg in 0.4 mL pre-filled syringe

Injection 15 mg in 0.6 mL pre-filled syringe

Injection 20 mg in 0.8 mL pre-filled syringe

Injection 25 mg in 1 mL pre-filled syringe

Statement of Compatibility with Human Rights

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

National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2022 (No. 2)

(PB 13 of 2022)

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 *National Health (Continued Dispensing – Emergency Measures) Amendment Determination 2022 (No. 2)* (the Instrument) amends the *National Health (Continued Dispensing – Emergency Measures) Determination 2020* (the Principal Instrument) which specifies the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the *National Health Act 1953* without a prescription, and the conditions for such a supply ('Continued Dispensing').

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 health and social security.

The Right to Social Security

The right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 UN Committee on Economic Social and Cultural Rights (the Committee) reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

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 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.

Analysis

This Instrument advances the right to health and the right to social security by ensuring that amendments to the Listing Instrument, that affect the pharmaceutical benefits that may be supplied as a Continued Dispensing supply, are made concurrently. The amendments made by this Instrument reflect amendments to the Listing Instrument, which commence on the same day.

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 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. This Instrument continues to provide the option for patients to have subsidised access to eligible PBS medicines through continued dispensing arrangements, during the COVID-19 pandemic.

Forms of the listed drugs cefotaxime and methotrexate were removed from this Instrument in accordance with the deletion of the forms from the Listing Instrument.

Sponsors are private entities that make their own decisions regarding their products and cannot be compelled by the Government to continue to list a product on the PBS. When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

The drug Cefotaxime in the form Powder for injection 2 g (as sodium) was requested to be delisted from the PBS by the sponsor due to the product no longer being commercially viable. The PBAC considered this request at its meeting in March 2021 and advised that the delisting of cefotaxime would not result in an unmet clinical need.

The drug Methotrexate in the forms Injection 7.5 mg in 0.3 mL pre-filled syringe, Injection 10 mg in 0.4 mL pre-filled syringe, Injection 15 mg in 0.6 mL pre-filled syringe, Injection 20 mg in 0.8 mL pre-filled syringe, and Injection 25 mg in 1 mL pre-filled syringe were requested to be delisted from the PBS by the sponsor due to the product no longer being commercially viable. The PBAC considered this request at its meeting in November 2020 and advised that the delisting of methotrexate would result in an unmet clinical need. The sponsor subsequently deregistered these forms of Methotrexate from the Australian Register of Therapeutic Goods effective on 30 June 2021.

Conclusion

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

Nikolai Tsyganov
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health