

Legislation (National Health Instruments) Sunset-altering Declaration 2022

EXPLANATORY STATEMENT

Issued by the Attorney-General in compliance with
section 15G of the *Legislation Act 2003*

INTRODUCTION

The *Legislation (National Health Instruments) Sunset-altering Declaration 2022* (the Declaration) is made under subsection 51A(1) of the *Legislation Act 2003* (Cth) (the Legislation Act). It is a legislative instrument for the purposes of the Legislation Act and must be registered on the Federal Register of Legislation. The Declaration is subject to the disallowance provisions of the Legislation Act.

OUTLINE

Sunsetting is the automatic repeal of legislative instruments after a fixed period. The Australian Government's sunsetting framework is established under Part 4 of Chapter 3 of the Legislation Act. The purpose of the sunsetting framework is to ensure that legislative instruments are kept up to date and only remain in force for so long as they are needed.

Subsection 50(1) of the Legislation Act provides that a legislative instrument is automatically repealed on the 1 April or 1 October immediately on or following the tenth anniversary of its registration.

Under subsection 51A(1) of the Legislation Act, the Attorney-General may issue a declaration aligning the sunsetting days of two or more instruments, if satisfied on application by the rule-maker/s of the relevant instruments that:

- (a) all the instruments to be reviewed:
 - i) would (in the absence of a declaration made under section 51A of the Legislation Act) be repealed by section 50 or 51 of the Legislation Act; and
 - ii) are or will be the subject of a single review; and
- (b) the making of the declaration will facilitate the undertaking of the review or the implementation of its findings.

The objective of issuing a sunset-altering declaration is to facilitate either:

- the undertaking of a single review into the fitness-for-purpose of two or more thematically related legislative instruments, or
- the implementation of such a review's findings.

This reduces administrative burden as well as the possibility of legislative inconsistencies arising from reviewing and replacing related legislation at different times.

The Declaration aligns the sunsetting dates of the following instruments to 1 April 2024 (together, 'the National Health Instruments'):

- (a) the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (Chemotherapy Arrangement);

- (b) the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PBS Listing Instrument);
- (c) the *National Health (Prescriber bag supplies) Determination 2012* (Prescriber Bag Determination).

Prior to the commencement of the Declaration, the PBS Listing Instrument and the Prescriber Bag Determination were scheduled to sunset on 1 October 2022 and the Chemotherapy Arrangement was scheduled to sunset on 1 April 2024.

PROCESS BEFORE DECLARATION WAS MADE

Regulatory impact analysis

Sunset-altering declarations are machinery of government instruments, and are therefore not subject to the regulatory impact assessment requirements set out by the Office of Best Practice Regulation (OBPR). The OBPR reference for this standing exemption is ID 19486.

Consultation before making

Before the Declaration was issued, the Attorney-General considered the general obligation to consult imposed by section 17 of the Legislation Act.

The National Health Instruments are made under the *National Health Act 1953* (Cth) (National Health Act). The application for alignment has been informed by consultations with Services Australia, the Department of Veterans' Affairs and the Australian Digital Health Agency.

In conducting the thematic review, the Department of Health and Aged Care will consult Services Australia, the Department of Veterans Affairs, Medicines Australia, the Generic and Biosimilar Medicines Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia as well as key patient interest groups.

Statutory preconditions relevant to the Declaration

In order to align the sunset day of two or more instruments, the Attorney-General must be satisfied on written application from the relevant rule-maker/s that the statutory conditions in paragraphs 51A(1)(a) and (b) of the Legislation Act are met. The statutory conditions are that:

- (a) all the instruments to be reviewed:
 - i) would (in the absence of a declaration made under section 51A of the Legislation Act) be repealed by section 50 or 51 of the Legislation Act; and
 - ii) are or will be the subject of a single review; and
- (b) the making of the declaration will facilitate the undertaking of the review or the implementation of its findings.

In terms of process, the Legislation Act requires:

- (a) the responsible rule-maker/s to apply to the Attorney-General
- (b) the Attorney-General to be satisfied of the statutory conditions, and
- (c) the Attorney-General to make a declaration, which is a legislative instrument and subject to disallowance.

For the purposes of section 6 of the Legislation Act, the Minister for Health and Aged Care, the Hon Mark Butler MP, is the rule maker of the National Health Instruments.

Minister Butler provided a written application to the Attorney-General seeking an alignment of the relevant sunseting days for the National Health Instruments. On consideration of this application, the Attorney-General was satisfied that the criteria in paragraphs 51A(1)(a) and (b) of the Legislation Act were met.

Statement of Reasons for issuing of the Declaration

For the purposes of subsection 51A(4) of the Legislation Act, this section sets out the statement of reasons for the issue of the declaration.

The Declaration aligns the sunseting dates for the National Health Instruments to enable the Department of Health and Aged Care to conduct a thematic review of the instruments. These instruments are key, and otherwise representative, components of Australia's Pharmaceutical Benefits Scheme (PBS). The PBS is a central feature of Medicare and provides the basis for timely, reliable and affordable access by Australians to necessary medicines. The National Health Instruments support the administration of the PBS, in particular the PBS Listing Instrument, which determines the medicines that may be supplied to patients at Government-subsidised prices.

The rationale for a thematic review of the PBS instruments is the substantial thematic connection between the instruments and their associated interdependence to support the efficient administration of the PBS. The review would address the significant complexity and intersection of the instruments by enhancing the readability of the instruments, minimising duplication and promoting greater clarity. This would include streamlining and simplifying the structure and content of the National Health Instruments to promote greater consistency in drafting, particularly with respect to the numerous cross-references.

As the National Health Instruments are interrelated and share a common theme, subjecting them to a single review will allow the rule-maker to consider aligning language, drafting and policy changes consistently. Their review will be similar in scope and stakeholders will only need to be consulted once, thus reducing the burden on their time. Administratively, it would be more efficient and effective to review the three instruments at the same time. This would align the sunseting dates of all three instruments to 1 April 2024.

This will be the first review of the National Health Instruments under the Legislation Act. A thematic review will broaden the scope of the review as it provides an opportunity for stakeholders to be consulted on more than one legislative instrument under the Legislation Act at the same time. The review will consider if the National Health Instruments are to be repealed, allowed to sunset or replaced (with or without changes).

The Chemotherapy Arrangement has been identified to form part of the alignment with the PBS Listing Instrument and the Prescriber Bag Instrument on account of the Chemotherapy Arrangement being highly characteristic of special arrangements made under the National Health Act. It is anticipated that the consideration of the Chemotherapy Arrangement in the context of the two other instruments will result in certain legal technical amendments that are likely to be extrapolated to other special arrangements made under the National Health Act.

A thematic review will facilitate an efficient and effective review process and enable consistent implementation of review findings. As such, the Declaration is consistent with the policy intent of the sunseting regime that legislative instruments should be kept up to date and only remain in force so long as they are needed.

More information

Further details on the provisions of the Declaration are provided in [Attachment A](#).

The National Health Instruments, which will now sunset on 1 April 2024 as specified in the Declaration, are available on the Federal Register of Legislation.

Further information may be requested from the Attorney-General's Department about the operation of the Declaration, and from the Department of Health and Aged Care about the National Health Instruments to which the Declaration applies.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

The *Legislation (National Health Instruments) Sunset-altering Declaration 2022* (the Declaration) is compatible with human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011* (the Human Rights Act).

Overview of the Declaration

The Declaration is made under subsection 51A(1) of the *Legislation Act 2003* (the Legislation Act). Under that subsection, the Attorney-General can align the sunseting days of two or more legislative instruments to 1 April or 1 October of a year that is up to five years later than the earliest sunseting day. The instruments specified in the declaration will then be repealed on the day specified in the declaration instead of the previously scheduled sunseting day. The instruments specified in the Declaration are (together, 'the National Health Instruments'):

- (a) the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*;
- (b) the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*; and
- (c) the *National Health (Prescriber bag supplies) Determination 2012*.

The Declaration aligns the sunseting dates of the National Health Instruments to 1 April 2024. Prior to the making of the Declaration, the second and third instruments were due to sunset on 1 October 2022 and the first instrument was due to sunset on 1 April 2024. The objective of issuing the Declaration is to facilitate the undertaking of a single thematic review of the National Health Instruments and the implementation of its findings.

Human Rights Implications

The National Health Instruments engage 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 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 a right to a system of health protection that 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.

The PBS advances the right to health and the right to social security by providing access to a benefit scheme that assists with advancement of this human right by providing patients with subsidised access to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee ensures that decisions made about subsidised access to medicines on the PBS are evidence-based.

A sunset-altering declaration may extend the operation of an instrument but does not change or affect the rights engaged under the original instrument, which have previously been subject to a Statement of Compatibility.

The Declaration itself is machinery in nature. It does not alter the arrangements in place under the National Health Instruments, but extends the operation of the instruments to 1 April 2024. The rights engaged under the National Health Instruments are not changed or substantially affected by the issuing of the Declaration.

Before issuing the Declaration, the Attorney-General was satisfied that all instruments specified in the Declaration would be subject to a single thematic review. A thematic review is an effective mechanism for determining whether the instruments are fit for purpose, identifying opportunities to update, streamline and clarify the operation of the instruments and, where appropriate, reducing unnecessary regulation. The human rights impact of the National Health Instruments will be considered during the proposed review, and addressed in the Statement of Compatibility of each replacement instrument.

Conclusion

The Declaration is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the Human Rights Act, as it does not raise any human rights issues, and ensures that any proposal to make a replacement instrument will be subject to parliamentary oversight and scrutiny.

NOTES ON THE DECLARATION

Section 1 Name

This section provides for the Declaration to be named the *Legislation (National Health Instruments) Sunset-altering Declaration 2022*. The declaration may be cited by that name.

Section 2 Commencement

This section provides for the Declaration to commence on the day after it is registered.

Section 3 Authority

This section provides that the Declaration is made under subsection 51A(1) of the *Legislation Act 2003*.

Section 4 Aligning of sunseting

This section provides that the following instruments are repealed by section 51A of the *Legislation Act 2003* on 1 April 2024:

- the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*;
- the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*; and
- the *National Health (Prescriber bag supplies) Determination 2012*.

1 April 2024 is the aligned sunseting day for those instruments, which would otherwise have sunset on 1 April 2024, 1 October 2022 and 1 October 2022 respectively.

Section 5 Repeal of this instrument

This section provides that the Declaration is repealed at the start of 2 April 2024.