

Legislation (Deferral of Sunsetting—National Health (Immunisation Program—Designated Vaccines) Determination) Certificate 2024

EXPLANATORY STATEMENT

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

INTRODUCTION

The *Legislation (Deferral of Sunsetting—National Health (Immunisation Program—Designated Vaccines) Determination) Certificate 2024* (the Certificate) is made under paragraph 51(1)(c) of the *Legislation Act 2003* (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 Certificate will be subjected to the disallowance provisions of the Legislation Act as the deferred sunsetting day specified in the Certificate is after the first anniversary of the originally scheduled sunsetting day, which means that subsection 51(4) of that Act (which provides an exemption from disallowance for deferrals of 12 months or less) does not apply.

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Subsection 50(1) of the Legislation Act provides that a legislative instrument is automatically repealed on 1 April or 1 October immediately on or following the tenth anniversary of its registration. Under paragraph 51(1)(c) of the Legislation Act the Attorney-General can issue a certificate to defer the sunsetting day of an instrument for a period of either 6, 12, 18 or 24 months.

The instrument will then be repealed on the day specified in the certificate instead of the previously scheduled sunsetting day. This allows instruments to continue to be in force for a further but limited period of time after the date on which they would otherwise sunset. This removes the administrative burden of remaking instruments which would have a limited duration prior to their repeal and

potential replacement, or where circumstances prevent the making of replacement instruments prior to the sunseting day.

The Certificate defers the sunseting date of *National Health (Immunisation Program—Designated Vaccines) Determination 2014 (No.1)* ('Determination') by 24 months from 1 October 2024 to 1 October 2026.

The ability to defer sunseting dates is an integral part of the sunseting framework. It provides the necessary flexibility to ensure the standard 10-year sunseting period does not result in unintended consequences or impose an unreasonable administrative burden on Commonwealth agencies or the Parliament. In this case, the Determination is expected to be remade within 24 months of the sunseting date as a result of a review of the instrument being conducted by the Department of Health and Aged Care (the department). A 24-month deferral will allow time for the department to consider recommendations from a number of reviews and reform work currently underway and conduct consultation on how implementing each recommendation would impact the National Immunisation Program (NIP). If the Certificate were to be disallowed, there would not be enough time to properly review and remake the Instrument prior to the sunseting day.

PROCESS BEFORE CERTIFICATE WAS MADE

Regulatory impact analysis

Certificates of deferral of sunseting are machinery of government instruments, and are therefore not subject to the regulatory impact assessment requirements set out by the Office of Impact Analysis (OIA). The OIA reference for this standing exemption is ID19633.

Consultation before making

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

The Determination is made under section 9B of the *National Health Act 1953*. Subsection 9B(1) states that the Minister may provide, or arrange for the provision of, designated vaccines and goods or services that are associated with, or incidental to, the provision or administration of designated vaccines. Subsection 9B(2) provides that the Minister may, by legislative instrument, determine that a specified vaccine is a designated vaccine for the purposes of this Act. Subsection 9B(5) provides that in addition to specifying a vaccine, a determination under subsection (2) may specify the circumstances in which the vaccine may be provided.

The Determination provides the supporting legislating framework for the National Immunisation Program (NIP), listing the designated vaccines available on the NIP, and detailing the circumstances in which the vaccines may be provided.

The NIP provides free vaccines to eligible people to help reduce diseases that can be prevented by vaccination. It provides protection to Australians and is a cost-effective tool for reducing the burden on the public health system. Ensuring that the legislation supporting the NIP is agile and sustainable into the future is vital to its continued success.

The Department of Health and Aged Care is undertaking reviews and reform work that will directly inform the replacement instrument for the Determination. The aim of these reviews is to ensure the NIP and associated legislative framework is fit-for-purpose, sustainable and responsive to the current and future immunisation landscape.

Stakeholders will be consulted to inform the reviews and reform work. This consultation includes engaging with patients, consumers, industry, priority population groups, state and territory representatives, and advisory bodies such as the Australian Technical Advisory Group on Immunisation and the Pharmaceutical Benefits Advisory Committee. The information collected will identify priorities and potential opportunities for the legislative framework supporting the NIP.

Certificates of deferral are machinery in nature, and enable legislative instruments that would otherwise sunset to remain in force for a further, but strictly limited, period of time. This will minimise the administrative burden on stakeholders associated with consultation on a deferral that will only have effect for a limited amount of time. Any replacement instrument will be subject to further consultation and parliamentary oversight, including oversight of whether adequate consultation occurred with persons likely to be affected by the replacement instruments.

A 24-month deferral will allow sufficient time for the Department of Health and Aged Care to implement the recommendations of relevant reviews and will avoid the need to remake the Determination in its current form for the short period of time before it is repealed and a replacement instrument is made. As such, given that deferral of the sunseting date of the Determination is consistent with the policy intent of the sunseting regime and does not significantly alter existing arrangements, appropriate consultation has occurred for the purposes of section 17 of the Legislation Act.

Statutory preconditions relevant to the Certificate

If the statutory conditions in section 51 of the Legislation Act are met, an instrument's sunseting day can be deferred for 6, 12, 18 or 24 months by means of a certificate made under that section. In terms of process, the Legislation Act requires:

- a) the responsible rule-maker to apply to the Attorney-General in writing, and
- b) the Attorney-General to be satisfied that:
 - (i) the instrument would (apart from the operation of the sunseting provisions) be likely to cease to be in force within 24 months after its sunseting day
 - (ii) the proposed replacement instrument will not be able to be completed before the sunseting day for reasons that the rule-maker could not have foreseen and avoided
 - (iii) the dissolution or expiration of the House of Representatives or the prorogation of the Parliament renders it inappropriate to make a replacement instrument before a new government is formed, or
 - (iv) the Attorney-General has approved Part 4 of Chapter 3 of the Legislation Act (Sunsetting) not applying to that instrument, and
- c) the Attorney-General to issue a certificate. The explanatory statement for the certificate must include a statement of reasons for the issue of the certificate.

The rule-maker for the Determination is the Assistant Secretary of the Immunisation Reform Branch in the National Immunisation Division of the Department of Health and Aged Care. Section 9B of the *National Health Act 1953* provides the Minister for Health and Aged Care with the power to make the Determination. The Minister has delegated this power to an officer occupying, or performing the duties of, the position of SES Band 2 or SES Band 1 in the National Immunisation Division in the Primary and Community Care Group in the department, under section 7 of the *National Health (Minister) Delegation (No.1) 2023*.

The rule-maker provided a written application to the Attorney-General seeking a certificate of deferral of sunseting for the Instrument. Based on the information contained in the statement of reasons below, the Attorney General is satisfied that the Determination would, apart from the operation of Part 4 of Chapter 3 of the Legislation Act, be likely to cease to be in force within 24 months after its sunseting day. As such, the criterion in subparagraph 51(1)(b)(i) of the Legislation Act is met.

Statement of Reasons for issuing of the Certificate

For the purposes of subsection 51(5) of the Legislation Act this section sets out the statement of reasons for issuing the Certificate.

The Certificate defers the sunseting date of the Determination by 24 months to 1 October 2026 to enable the Department of Health and Aged Care to implement the recommendations of relevant reviews, including the targeted National Immunisation Program (NIP) review of the NIP listing and procurement processes, review of the legislative framework, and the Health Technology Assessment Policy and Methods Review.

The NIP Review conducted as part of continuous program management, considered how to shape a program that is agile, effective, and efficient in delivering vaccines, to determine if:

- the program is able to respond to future emergency disease outbreaks, respiratory vaccinations, and the development of new immunisation technologies; and
- the NIP listing process (the regulatory steps that must occur before a vaccine is supplied), procurement, and contract processes can be optimised so they are agile and flexible.

The review was finalised in June 2024, with an action plan to be developed by the Department of Health and Aged Care.

The Health Technology Assessment Policy and Methods Review aims to review the current policy and methods used by the Pharmaceutical Benefits Advisory Committee (PBAC) to assess new medicines and vaccines for listing on the Pharmaceutical Benefits Scheme (PBS) and the NIP. Recommendations from the review were finalised in May 2024, with consideration by Government currently underway.

A review of the legislative framework supporting the NIP, the *National Health Act 1953* and the Determination, is planned for the second half of 2024. This review will identify if the current legislation is sufficiently responsive to emerging technologies and health emergencies.

To enable the new Determination to reflect the recommendations from the reviews currently underway, the Department of Health and Aged Care requires a deferral of the sunset date of the Determination by 24 months.

Accordingly, the Determination will likely cease to be in force in its current form within 24 months of its original sunseting date.

More information

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

The Determination which is subject to the Certificate, and which will now sunset at a later day as specified in the Certificate, is available on the Federal Register of Legislation.

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

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

The *Legislation (Deferral of Sunsetting—National Health (Immunisation Program—Designated Vaccines) Determination) 2014 Certificate 2024* (the Certificate) 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 Certificate

The Certificate is made under paragraph 51(1)(c) of the *Legislation Act 2003*. Under that paragraph the Attorney-General can issue a certificate to defer the sunsetting day of an instrument for a period of either 6, 12, 18 or 24 months. The instrument will then be repealed on the day specified in the Certificate instead of the originally scheduled sunsetting day. The Instrument specified in the Certificate is the *National Health (Immunisation Program — Designated Vaccines) Determination 2014 (No. 1)* (the Determination).

The Determination is expected to be repealed and replaced within 24 months of its scheduled sunsetting day as part of the review of the current legislative framework.

The Certificate allows the Determination to continue to be in force for a further, but limited, period of time when it would otherwise sunset. This removes the administrative burden of remaking the Instrument which would have a limited duration prior to its expected repeal and replacement, or where circumstances prevent the making of a replacement instrument prior to the sunsetting day.

Human Rights Implications

A certificate of deferral of sunsetting extends the operation of the instrument but does not change or affect the rights engaged under the original instrument.

The Determination engages certain rights and freedoms declared by the international instruments set out in section 3 of the Human Rights Act.

The Determination provides the legislative framework that supports the NIP and lists the designated vaccines available on the NIP and details the circumstances in which these vaccines may be provided. The NIP provides free vaccines to eligible people and provides protection to Australians in a cost-effective manner by reducing the strain on the public health system.

Article 12 of the International Covenant on Economic, Social and Cultural Rights recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Determination engages this right to health as it provides free access for eligible people to a designated vaccine and protects individuals and the community against vaccine preventable disease.

Deferring the sunseting of the Determination will continue the circumstances in which vaccines are delivered to eligible people. This is reasonable and necessary to ensure that access to vaccinations is still available while ongoing work is undertaken by the Department of Health and Aged Care to strengthen the legislative framework supporting the *National Health Act 1953*.

Therefore, overall, the Determination is compatible with human rights.

Before issuing the Certificate, the Attorney-General was satisfied that the Determination would, apart from the operation of the sunseting provisions, cease to be in force within 24 months of its sunseting date. Issuing a certificate of deferral therefore avoids the need to replace the Instrument in its current form for a short period of time before it is expected to be repealed and replaced.

Instruments that are replaced will be subject to parliamentary scrutiny and oversight through the disallowance processes unless otherwise exempt. The human rights impact of the remade Determination will be assessed at the time it is made, including through the requirement to prepare a Statement of Compatibility with Human Rights.

Conclusion

This Certificate 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 CERTIFICATE

Section 1 Name

This section provides that the Certificate is named the *Legislation (Deferral of Sunsetting—National Health (Immunisation Program—Designated Vaccines) Determination) Certificate 2024*. The Certificate may be cited by this name.

Section 2 Commencement

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

Section 3 Authority

This section provides that the Certificate is made under paragraph 51(1)(c) of the *Legislation Act 2003*.

Section 4 Deferral of sunseting

This section provides that the *National Health (Immunisation Program — Designated vaccines) Determination 2014 (No.1)*, for which the sunseting day is 1 October 2024, is repealed by section 51 of the *Legislation Act 2003* on 1 October 2026.

Section 5 Repeal of the instrument

This section provides that the Certificate is repealed at the start of 2 October 2026.