

Legislation (Deferral of Sunsetting—National Health (Efficient Funding of Chemotherapy) Special Arrangement) Certificate 2021

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 (Efficient Funding of Chemotherapy) Special Arrangement) Certificate 2021* (the Certificate) is made under paragraph 51(1)(c) of the *Legislation Act 2003* (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Subsection 50(1) of the Legislation Act provides that a legislative instrument is automatically repealed on 1 April or 1 October immediately on or following the tenth anniversary of its registration, unless it was registered on 1 January 2005. Legislative instruments registered on 1 January 2005 are subject to the staggered sunsetting timetable set out in subsection 50(2) of the Legislation Act.

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 six, 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 The instrument will then be repealed on the day specified in the certificate instead of the previously scheduled sunsetting day.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 when 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 sunsetting day.

The Certificate defers the sunsetting date of the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (the EFC Instrument) by 24 months from 1 April 2022 to 1 April 2024.

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 Best Practice Regulation (OBPR). The OBPR 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 Minister for Health, the Hon Greg Hunt MP, is the relevant rule-maker for the EFC Instrument for the purposes of section 6 of the Legislation Act. The Minister advised the Attorney-General of the reasons in support of issuing the Certificate.

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. Deferrals are most commonly used to enable an effective review of whether the deferred instrument continues to be fit for purpose taking into account anticipated policy or legislative changes.

As part of the 2020-21 Budget, the Australian Government agreed to a review of the current EFC arrangements. The EFC review will look at the impact and continuing suitability of current EFC arrangements and associated practices within the supply chain to ensure continuing access to these medicines.

In conducting the EFC review, the Government will examine whether the EFC Program supports patient access to chemotherapy medicines in an efficient and cost-effective manner. The Government may also consider whether a new or adjusted reimbursement framework is required to ensure ongoing access to these medicines and whether a new or adjusted framework may encourage innovation and collaboration across the EFC supply chain. The EFC review will include stakeholder consultation.

A 24 month deferral will allow sufficient time for consultation on the EFC review and for any changes to the EFC Program as a result of the review, to be properly considered and a replacement EFC Instrument made. The deferral will avoid the need to remake the EFC Instrument in its current form for the short period of time before it is repealed and a replacement instrument made. As such, deferral of the sunseting date of the EFC Instrument 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.

As 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, further consultation in relation to the deferral was considered unnecessary. As the EFC review will likely result in significant changes to the current EFC arrangements, stakeholder consultation is best undertaken as part of this process rather than the deferral. This will minimise the administrative burden on stakeholders associated with consultation on the deferral. Any replacement instrument will

be subject to further consultation and parliamentary oversight, including whether adequate consultation occurred with persons likely to be affected by the replacement instrument.

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 six, 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; or
 - (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; or
 - (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 EFC Instrument, the Minister for Health, the Hon Greg Hunt MP, provided a written application to the Attorney-General seeking a deferral of sunseting for the EFC Instrument. On the basis of the information contained in the statement of reasons below, the Attorney-General is satisfied that the EFC Instrument 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 the reasons for issuing the Certificate.

The EFC Instrument is made under subsection 100(1) of the *National Health Act 1953*. The EFC Program, governed by the EFC Instrument since 2011, provides funding for chemotherapy medicines that require reconstitution or preparation prior to infusion or injection to individual patients at public or private hospitals. Not all chemotherapy medicines are provided through this Program, but may be subsidised through the broader Pharmaceutical Benefits Scheme (PBS).

Preparation of these cytotoxic medicines requires specialised equipment and processes to protect health care workers compounding the medicine. The Program aims to minimise wastage and reduce costs to the Commonwealth by funding the lowest cost combination of vials of the medicines, and provide pharmacies with specific remuneration for compounding chemotherapy medicines for individual patients.

Since the establishment of the EFC Program, and increasingly in recent years, stakeholders have expressed varying views regarding the:

- Appropriateness of the compounding fees provided compared to the actual cost of compounding (including operational costs in relation to compounding in Therapeutic Goods Administration (TGA) licenced facilities)
- Administrative burden associated with claiming and payment for chemotherapy medicines dispensed from a range of pharmacy settings, and
- Appropriateness of the current EFC approach in ensuring all participants in the chemotherapy medicines supply chain are reimbursed fairly and appropriately.

As part of the 2020-21 Budget, the Australian Government agreed to a review of the current EFC arrangements. The EFC review will look at the impact and continuing suitability of current EFC arrangements and associated practices within the supply chain to ensure continuing access to these medicines.

In conducting the EFC review, the Government will examine whether the EFC Program supports patient access to chemotherapy medicines in an efficient and cost-effective manner. The Government may also consider whether a new or adjusted reimbursement framework is required to ensure ongoing access to these medicines and whether a new or adjusted framework may encourage innovation and collaboration across the EFC supply chain.

The EFC review will produce a final report no later than 30 June 2022. A 24 month deferral will allow sufficient time for any changes to the EFC Program as a result of the review, to be properly considered and a replacement EFC Instrument made. The deferral will avoid the need to remake the EFC Instrument in its current form for the short period of time before it is repealed and a replacement instrument made. As such, deferral of the sunseting date of the EFC Instrument 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 Certificate are provided in [Attachment A](#).

The EFC Instrument 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 about the EFC Instrument.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

The *Legislation (Deferral of Sunsetting—National Health (Efficient Funding of Chemotherapy) Special Arrangement) Certificate 2021* (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

This 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 six, 12, 18 or 24 months. The instrument will then be repealed on the day specified in the Certificate instead of the scheduled sunsetting day. The instrument specified in this Certificate is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (the EFC Instrument).

The EFC Instrument is expected to be repealed and replaced within 24 months of its scheduled sunsetting date due to its repeal and replacement with a new instrument as part of a Government review of the current Efficient Funding of Chemotherapy (EFC) arrangements. The EFC review will look at the impact and continuing suitability of current EFC arrangements and associated practices within the supply chain to ensure continuing access to these medicines.

In conducting the EFC review, the Government will examine whether the EFC Program supports patient access to chemotherapy medicines in an efficient and cost-effective manner. The Government may also consider whether a new or adjusted reimbursement framework is required to ensure ongoing access to these medicines and whether a new or adjusted framework may encourage innovation and collaboration across the EFC supply chain.

A 24 month deferral will allow sufficient time for any changes to the EFC Program as a result of the review, to be properly considered and a replacement EFC Instrument made. The Certificate allows the EFC Instrument 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 an instrument which would have a limited duration prior to its repeal and potential replacement, or where circumstances prevent the making of replacement instruments prior to the sunsetting day.

As such, deferral of the sunsetting date of the EFC Instrument is consistent with the policy intent of the sunsetting regime, that legislative instruments should be kept up to date and only remain in force so long as they are needed.

Human rights implications

The Statement of Compatibility for a certificate of deferral of sunsetting focuses on the effect of the deferral instrument, rather than the substantive effect of continuing the instruments that have been deferred.

Before issuing the Certificate, the Attorney-General was satisfied that the EFC Instrument would, apart from the operation of the sunsetting provisions, cease to be in force within 24 months of its sunsetting date. Issuing a certificate of deferral therefore avoids the need to replace the EFC Instrument in its current form for a short period of time before it is expected to be repealed and possibly 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 instrument will be assessed at that time, including through the requirement to prepare a further 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 by ensuring that any proposal to make a replacement instrument that unduly limits human rights and freedoms will be subject to parliamentary oversight and scrutiny.

ATTACHMENT A

NOTES ON THE CERTIFICATE

Section 1 Name

This section provides that the Certificate is named the *Legislation (Deferral of Sunsetting—National Health (Efficient Funding of Chemotherapy) Special Arrangement) Certificate 2021*. 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.

Section 4 Deferral of sunseting

This section provides that the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, for which the sunseting day is 1 April 2022, is repealed by section 51 of the Legislation Act on 1 April 2024.

Section 5 Repeal of the instrument

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