# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Medicines Watch List) Amendment Determination 2025*

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA") within the Australian Government Department of Health and Aged Care ("the Department").

The Act provides a framework for the mandatory reporting of shortages or discontinuations of certain medicines that are reportable medicines. Under subsections 30EF(1) and 30EG(1), the timeframe for reporting a shortage or discontinuation of a reportable medicine that is of *critical impact* is more immediate than for other reportable medicines. Subsection 30EF(2) of the Act provides that the shortage of a medicine in Australia at a particular time has a critical impact if, at the time, the medicine is included in an instrument under section 30EJ. Section 30EG(2) of the Act provides that the discontinuation of the supply of a medicine in Australia is likely to be of critical impact if, when the discontinuation decision is made, the medicine is included in an instrument under section 30EJ.

Subsection 30EJ(1) of the Act relevantly provides that the Minister may, by legislative instrument, determine medicines for the purposes of subsections 30EF(2) and 30EG(2) of the Act. The effect of a medicine being included in such an instrument is that the timeframes for reporting a shortage or discontinuation of the medicine are the timeframes that apply to a shortage or discontinuation of critical impact.

The *Therapeutic Goods (Medicines Watch List) Determination 2018* ("the Principal Determination") is made under subsection 30EJ(1) of the Act. The Principal Determination identifies reportable medicines for which a shortage would, or a decision by the medicine's sponsor to permanently discontinue its supply may, be of critical impact for the purposes of the reporting requirements for medicines shortages and discontinuations in sections 30EF and 30EG of the Act.

The *Therapeutic Goods (Medicines Watch List) Amendment Determination 2025* ("the Amendment Determination") amends the Principal Determination to refer to the National Immunisation Program Schedule ("the NIP Schedule") as in force or existing on 1 March 2025. This is intended to incorporate any vaccines that have been added to the NIP Schedule since 2018.

**Background**

The Act provides for mandatory reporting to the Secretary of a shortage or discontinuation of reportable medicines. Reportable medicines are defined in section 30EH of the Act as registered goods that contain one or more substances in Schedule 4 or 8 to the current Poisons Standard or are determined in an instrument. They are medicines that are particularly important for the health of patients who need to take them so it is in the interests of public health for the mandatory reporting requirements to apply.

The mandatory requirements are set out in:

- section 30EF of the Act, which requires notification to the Secretary of any shortage of a reportable medicine;
- section 30EFA of the Act, which requires notification to the Secretary of a change to the period of a shortage or resolution of a shortage; and
- section 30EG of the Act, which requires notification to the Secretary of a decision to discontinue the supply of a reportable medicine in Australia.

The time period within which sponsors are required to report a shortage or discontinuation (or change in the period of the shortage or resolution of a shortage) of reportable medicines depends on whether the shortage or discontinuation is of 'critical impact'. Under subsection 30EF(1) of the Act, shortages of "critical impact" must be reported to the Secretary, using the approved form, as soon as possible but no later than 2 working days after the sponsor knows, or ought to have reasonably known, of the shortage. Under subsection 30EG(1) of the Act, discontinuations of 'critical impact' must be notified at least 12 months before the discontinuation would occur, or otherwise as soon as possible after the decision to discontinue supply is made.

Subsections 30EF(2) and 30EG(2) of the Act provide that a shortage or discontinuation, respectively, are of critical impact if the medicine that is the subject of the shortage or discontinuation is determined in an instrument made under section 30EJ.

The Principal Determination is made under subsection 30EJ(1) of the Act and lists medicines, in Schedule 1 to the Principal Determination, in relation to which a shortage or discontinuation would be of critical impact.

**Purpose**

Item 5 of Schedule 1 to the Principal Determination provides that medicines that are a vaccine included in the NIP Schedule, as in force or existing at 1 July 2018, are determined for the purposes of subsections 30EF(2) and 30EG(2) of the Act. A shortage or discontinuation of such a vaccine would be of critical impact.

The Amendment Determination amends the Principal Determination to provide that medicines that are a vaccine included in the NIP Schedule, as in force or existing at 1 March 2025, are determined for the purposes of subsection 30EF(2) and 30EG(2) of the Act. This ensures that the most up to date version of the NIP Schedule is referred to in the Principal Determination, with the effect that any new vaccines that have been added to the NIP Schedule since 1 July 2018 will need to be the subject of more timely shortages and discontinuation notifications. This will help the TGA to identify and respond to shortages or discontinuations of critical vaccines that have been added to the NIP schedule since 1 July 2018.

The NIP Schedule details a list of vaccines recommended to be given at specific times throughout a person's life, providing immunity against diseases which can cause serious ongoing health conditions, hospitalisation and potentially death. As at 1 March 2025, the NIP Schedule includes new vaccines for respiratory syncytial virus, meningococcal disease caused by serogroups A, B, C, W and Y, shingles, diphtheria, tetanus, pertussis (whooping cough), hepatitis B, polio, Haemophilus influenzae type b (Hib), and seasonal influenza.

**Statutory requirements**

Subsection 30EJ(2) of the Act provides that the Minister must not determine a medicine for the purposes of subsections 30EF(2) and 30EG(2) unless the Minister is satisfied that any shortage of the medicine, or any permanent discontinuation of the supply of the medicine, in Australia has the potential to result in significant morbidity in patients in Australia or the death of one or more patients in Australia.

The new vaccines included in the NIP Schedule since 1 July 2018 are supplied in Australia free of charge to those with (or eligible to obtain) a Medicare card. The NIP aims to increase national immunisation coverage to help reduce diseases that can be prevented by vaccines. Such diseases could result in significant morbidity in, or the death of, patients in Australia. Vaccines on the NIP Schedule are intended to be given at specific times throughout a person's life, where delays in receiving the vaccine may affect a person's optimal protection against serious disease.

The rule-maker is therefore satisfied that any shortage of the new vaccines, or any permanent discontinuation of the supply of the new vaccines, in Australia has the potential to result in significant morbidity in patients in Australia or the death of one or more patients in Australia.

**Incorporation by reference**

The Principal Determination incorporates by reference the document titled *'National Immunisation Program Schedule'*, which is published by the Department. This document provides a list of recommended vaccines for patients at various stages of life, and all vaccines included in the schedule are free.

The Amendment Determination incorporates the NIP Schedule as in force or existing on 1 March 2025, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*, which permits a legislative instrument to incorporate a document (that is not an Act or legislative instrument) as it exists at, or before, the time the instrument commences. The NIP Schedule is available for free from the Department of Health and Aged Care website and may be accessed at www.health.gov.au/resources/publications/national-immunisation-program-schedule.

**Consultation**

Between 23 February 2024 and 13 March 2024, the TGA publicly consulted about the broad challenges and barriers associated with medicine shortages and discontinuations. The TGA received 221 submissions that provided feedback on a range of experiences and views on medicine shortage impacts and improvement opportunities. To further identify opportunities for improvement, in June 2024 the TGA held targeted focus groups with peak organisations across the medicine supply chain to discuss priority areas for potential reform. The need to maintain currency of the medicine shortages regulatory framework, including the Principal Determination, was raised by peak health organisations during these discussions and in subsequent engagements.

The amendment to capture the most up to date version of the NIP Schedule is a machinery change to maintain the Principal Determination's currency and align with the Australian Government's national immunisation policy and further specific consultation on this amendment was not conducted. The Office of Impact Analysis has been consulted and advised that detailed analysis is not required under the Australian Government's Policy Impact Analysis Framework (OIA24-08740).

**Other details**

Details of the Amendment Determination are set out in **Attachment A**.

The Amendment Determination is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences the day after registration on the Federal Register of Legislation.

**Attachment A**

**Details of the *Therapeutic Goods (Medicines Watch List) Amendment Determination 2025***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Medicines Watch List) Amendment Determination 2025* ("the Amendment Determination").

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on the day after it is registered on the Federal Register of Legislation.

**Section 3 – Authority**

This section provides that the legislative authority for making the Amendment Determination is subsection 30EJ(1) of the *Therapeutic Goods Act 1989*.

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This Amendment Determination is made in accordance with that provision.

**Section 4 – Schedules**

This section gives legal effect to the amendments in Schedule 1 to the Amendment Order.

**Schedule 1 – Amendments**

This Schedule amends the *Therapeutic Goods (Medicines Watch List) Determination 2018* ("the Principal Determination").

**Item 1 – Schedule 1 (cell at table item 5, column 2)**

This item amends paragraph (a) in column 2 of item 5 of Schedule 1 to the Principal Determination to refer to the National Immunisation Program Schedule ("the NIP Schedule") as in force or existing at 1 March 2025. This would reference the most recent version of the NIP Schedule ensures that Schedule 1 to the Principal Determination reflects the most current version of the NIP Schedule and includes those vaccines that have been included in the NIP Schedule since 1 July 2018.

## Statement of Compatibility with Human Rights

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

***Therapeutic Goods (Medicines Watch List) Amendment Determination 2025***

This disallowable 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 legislative instrument**

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**Human rights implications**

The Amendment Determination promotes the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR"). This right is understood as the right of everyone to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a

‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Determination supports the right to health by requiring sponsors to notify the TGA of a shortage or discontinuation of all medicines currently included in the NIP Schedule, within a shorter timeframe that reflects the “critical impact” that such a shortage or discontinuation would have. Ensuring all medicines currently included in the NIP Schedule are prescribed in the Principal Determination for the purposes of the mandatory reporting requirements for shortages and discontinuations supports will enable patients and health practitioners to be better informed, and informed earlier, about shortages of vaccines in the NIP Schedule that affect them. It will also place the TGA, other stakeholders, health practitioners and patients in a better position to take steps to alleviate the impact of a shortage or discontinuation on patient health.

**Conclusion**

The Amendment Determination is compatible with human rights because it supports the right to health in Article 12 of the ICESCR as outlined above, and otherwise does not raise any human rights issues.