EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Reportable Medicines) 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 Act provides a framework for the mandatory reporting of shortages or discontinuations of certain medicines that are reportable medicines. Under section 30EH(1) of the Act, reportable medicines are registered medicines that either contain one or more Schedule 4 (Prescription Only Medicine) or Schedule 8 (Controlled Drug) substances, or are determined in an instrument made under subsection 30EH(2) of the Act. Subsection 30EH(2) of the Act provides that the Minister may, by legislative instrument, determine medicines, for the purposes of subparagraph 30EH(1)(b)(ii), with the effect that such medicines are reportable medicines.

The *Therapeutic Goods (Reportable Medicines) Determination 2025* ("the Determination") is made under subsection 30EH(2) of the Act. The purpose of the Determination is to determine medicines that are registered goods to be reportable medicines (for the purposes of subparagraph 30EH(1)(b)(ii) of the Act). Such medicines must comply with the mandatory reporting requirements relating to medicine shortages and discontinuations under sections 30EF, 30EFA and 30EG of the Act.

The Determination repeals and replaces the *Therapeutic Goods (Reportable Medicines) Determination 2018* ("the former Determination"). The Determination includes the same medicines that were determined under the former Determination, and also determines a number of additional medicines to be reportable medicines.

Background

Medicine shortages can occur for various reasons, ranging from shortages of raw materials to national disasters, logistical difficulties, or unexpected increases in demand. Unfortunately, some are unavoidable and can cause significant impact. If there are no alternative medicines available (such as generic versions of a medicine), patients may be unable to obtain the medicine they need or are prescribed. This impedes timely availability of medicines and risks interruption to treatment, which can impact patient health and cause anxiety and stress for patients.

In 2019, a mandatory medicine shortages and discontinuations reporting scheme ("mandatory reporting scheme") commenced, which replaced an early voluntary notification scheme. The mandatory reporting scheme involved the mandatory reporting of all shortages and discontinuations of certain medicines, the publication of information about those shortages or discontinuations, and greater transparency regarding the mitigation actions that could be taken by the TGA. Through the mandatory reporting scheme, the TGA receives and publishes reports of shortages and discontinuations of prescription and certain over-the-counter medicines. The TGA works closely with sponsors and other stakeholders to respond to shortages and limit their impacts.

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

These requirements apply to *reportable medicines*, which is defined in section 30EH of the Act. Reportable medicines are registered goods (i.e., goods registered in the Australian Register of Therapeutic Goods ("the Register")) that are a medicine that either:

1. contains a substance included in Schedule 4 or 8 to the current Poisons Standard; or
2. is determined in an instrument under section 30EH(2).

The Determination is made under subsection 30EH(2) for the purpose of determining medicines that are reportable medicines.

The effect of the inclusion of a medicine in the Determination is that the requirements of the mandatory reporting scheme principally set out in sections 30EF, 30EFA and 30EG of the Act will apply to the person in relation to whom the goods are included in the Register. Medicines included in the Determination are particularly important for the health of patients who need to take the medicines, and are therefore medicines for which it would be in the interests of public health for the mandatory reporting requirements to apply. The reporting of such shortages and discontinuations supports timely action by the TGA, as well as other stakeholders, to address the shortage or discontinuation and attempt to minimise the detrimental impact a shortage or discontinuation may have on patients in Australia.

The TGA continues to rely on voluntary reporting of shortages by sponsors of medicines that are not reportable medicines. However, the voluntary approach has not been effective in all situations. Shortages of medicines that are not reportable medicines that have impacted the Australian community include, for example, certain non-prescription medicines listed on the Pharmaceutical Benefits Scheme ("PBS") (e.g. permethrin cream, which is a topical scabies treatment).

Purpose

The purpose of the Determination is to determine medicines, with the effect that those medicines are reportable medicines and will be subject to the mandatory reporting scheme.

Section 5 of the Determination provides that the medicines set out in Schedule 1 to the Determination are determined to be reportable medicines for the purposes of subparagraph 30EH(1)(b)(ii) of the Act.

The former Determination prescribed a number of non-prescription, registered medicines, which were considered critical to the health of patients in Australia, as reportable medicines. The Determination continues to provide that those medicines included in the former Determination are reportable medicines.

The Determination also determines additional medicines as reportable medicines. These are also medicines that are critical for the health of patients who need them and there would be a high risk to patient care if a shortage or discontinuation was to occur. These medicines were identified from the TGA's analysis of PBS medicines, the Medicines Watch List, previous shortages, and approvals of overseas alternative medicines where the registered medicines were unavailable or in short supply in Australia.

The new medicines specified in the Determination include, for example:

- medicines that contain one of cyproheptadine, pancreatic extract or theophylline;
- medicines that are in the dosage form of an injection that contain either phytomenadione, sodium bicarbonate or thiamine as the only active ingredient;
- medicines for intravenous phosphate supplementation that are in the dosage form of an injection or an infusion, and that contain one of dibasic potassium phosphate, dibasic sodium phosphate, monobasic potassium phosphate or monobasic sodium phosphate as an active ingredient;

- medicines for the treatment of poisonings or drug overdosage by oral ingestion that contain activated charcoal as an active ingredient; and
- medicines for the treatment of scabies that contain either benzyl benzoate or permethrin as an active ingredient.

The inclusion of these medicines as reportable medicines will enable the TGA to better monitor and alert the Australian public to a shortage or permanent discontinuation. It will also enable the TGA, in consultation with sponsors, to take steps to mitigate the impacts of a shortage or discontinuation, and to better inform health practitioners and consumers to minimise the impact of these events on patient health.

Statutory requirements

Subsection 30EH(3) provides that the Minister must not determine a medicine unless the Minister is satisfied that either the medicine is critical to the health of patients in Australia, or the notification to the Secretary of any shortage of the medicine, or of any decision to permanently discontinue the supply of the medicine, in Australia would be in the interests of public health, or both.

Many of the new medicines being added to the Determination are critical to the health of patients, including lifesaving treatments for conditions such as poisonings, drug overdose, cardiac arrest and severe electrolyte disturbances. Other medicines being added to the Determination, like barium sulfate and sodium chloride 0.9% injections or infusions, are considered critical to the timely provision of health care in Australia. Notification of a shortage or discontinuation of these medicines, as well as certain non-prescription medicines listed on the PBS, is in the interests of public health, so that timely action may be taken to minimise the impact on patients. Many of these medicines have limited suitable therapeutic alternatives, which further contributes to the need for mandatory reporting requirements to apply in the interests of public health.

The rule-maker is therefore satisfied that all the new medicines to be determined in the Determination as reportable medicines are critical to the health of patients in Australia, or a notification of a shortage or discontinuation in Australia would be in the interests of public health.

Consultation

Between 11 November 2024 and 13 January 2025, the TGA published a consultation paper and conducted a consultation, including in relation to the proposal to add more critical, non-prescription medicines to the list of reportable medicines. The TGA invited 109 key stakeholders to participate in the consultation, including all current sponsors of medicines directly impacted by the proposal.

The TGA received 39 submissions to the consultation, including from the pharmaceutical industry, government, health professionals and consumer organisations. There was extensive support for the TGA's proposal to add the identified non-prescription medicines to the Determination.

Several respondents suggested that additional medicines be added to the Determination. Following consultation with potentially affected sponsors, one extra non-prescription medicine, benzyl benzoate for the treatment of scabies, was added to the Determination.

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 Determination are set out in **Attachment A**.

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

Attachment A

Details of the *Therapeutic Goods (Reportable Medicines) Determination 2025*

Section 1 – Name

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

Section 2 – Commencement

This section provides that the 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 Determination is subsection 30EH(2) of the *Therapeutic Goods Act 1989* ("the Act").

Section 4 – Definitions

This section provides that the term "Act" used in the Determination is defined as meaning the *Therapeutic Goods Act 1989.* This section also notes that some expressions used in the Determination, including "active ingredient", "current Poisons Standard", "medicine", "registered goods" and "reportable medicine" have the same meaning as in the Act.

Section 5 – Reportable medicines

This section provides that the medicines set out in Schedule 1, being medicines that are registered goods, are determined to be reportable medicines for the purposes of subparagraph 30EH(1)(b)(ii) of the Act.

Section 6 – Repeals

This section provides that each instrument set out in Schedule 2, being the *Therapeutic Goods (Reportable Medicines) Determination 2018,* is repealed as set out in that Schedule.

Schedule 1 – Reportable Medicines

This Schedule lists the following reportable medicines for the purposes of section 5 of the Determination:

- medicines that contain one of cyproheptadine, levonorgestrel, pancreatic extract, theophylline or ulipristal;
- medicines that contain one of the following substances, subject to particular specifications as to dosage form, route of administration, or ingredients :
    - barium sulfate;
    - calcium gluconate;
    - folinic acid;
    - glucagon;
    - glyceryl trinitrate;
    - hydroxocobalamin;
    - isosorbide dinitrate;
    - magnesium sulfate;
    - mannitol;

    - monobasic sodium phosphate;
    - naloxone;
    - salbutamol;
    - terbutaline;
- medicines for the treatment of anaphylaxis or management of cardiac arrest, that contain adrenaline (epinephrine) as the only active ingredient;
- medicines that are in the dosage form of an injection that contain either phytomenadione, sodium bicarbonate or thiamine as the only active ingredient;
- medicines for intravenous phosphate supplementation that are in the dosage form of an injection or an infusion, and that contain one of dibasic potassium phosphate, dibasic sodium phosphate, monobasic potassium phosphate or monobasic sodium phosphate as an active ingredient;
- medicines that contain 0.9% sodium chloride as the only active ingredient, and are in the dosage form of an injection or an intravenous infusion;
- medicines for the treatment of poisonings that contain ethanol, sodium nitrite or sodium thiosulfate as an active ingredient;
- medicines for the treatment of poisonings or drug overdosage by oral ingestion that contain activated charcoal as an active ingredient;
- medicines for the treatment of scabies that contain either benzyl benzoate or permethrin as an active ingredient; and
- medicines for oral bicarbonate supplementation that contain sodium bicarbonate as an active ingredient.

Schedule 2 – Repeals

This Schedule provides for the repeal of the whole of the *Therapeutic Goods (Reportable Medicines) Determination 2018*.

Attachment B

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Reportable Medicines) 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 Determination takes positive steps to promote 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 Determination promotes the right to health by requiring sponsors to notify the TGA of a shortage or discontinuation of registered medicines that are reportable medicines. These medicines are critical for the health of patients who need them and pose a high risk to care if a shortage or discontinuation was to occur. By retaining some medicines within, and introducing additional medicines to, the mandatory reporting scheme, the Determination will enable patients and health practitioners to be better informed, and informed earlier, about shortages that affect them. It will also place the TGA, other stakeholders, health practitioners and patients in a better position to take steps to mitigate the impact of a shortage or discontinuation on patient health.

Conclusion

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