**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023*

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy, 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”).

Subsection 26BD(1) of the Act relevantly provides that a person may make an application to the Secretary for a recommendation by the Secretary that the Minister vary a determination made under section 26BB of the Act, which specifies permissible ingredients that may be included in listed medicines. Subsection 26BD(3) sets out the requirements for such an application, including that the application must be accompanied by information that is of a kind determined under subsection 26BD(8) and in a form determined under subsection 26BD(9). Subsections 26BD(8) and (9) provide that the Secretary may, by legislative instrument, determine a kind of information and a form of information that must accompany such an application.

The *Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023* (“the Determination”) is made under subsections 26BD(8) and (9) of the Act. The purpose of the Determination is to specify the kind of information that must accompany an application under section 26BD, for a recommendation by the Secretary that the Minister vary a determination made under section 26BB of the Act, as well as the form in which that information must be provided. The Determination provides clarity around the nature and level of information needed to support a potentially successful section 26BD application. In particular, the Determination provides clarity in relation to what the minimum requirements are for supporting information that must accompany new ingredient applications or applications to vary existing ingredient requirements.

**Background**

Subsection 26BB(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination specifying ingredients and, for some or all of those ingredients, requirements in relation to those ingredients being contained in a medicine. Under subsections 26BB(2), (2A) and (3) of the Act, such requirements may relate to particular ingredients not being contained in particular medicines, or being contained in particular medicines only in specified circumstances, or to permitted concentrations or total amounts of an ingredient in a medicine.

A legislative instrument made under section 26BB of the Act (“section 26BB determination”) specifies those ingredients that may be contained in a medicine that is listed in the Australian Register of Therapeutic Goods (“the Register”) under sections 26A or 26AE of the Act, and to specify requirements in relation to the inclusion of those ingredients in such medicines.

In accordance with subsections 26A(2) and 26AB(2) of the Act, sponsors that make an application under section 23 of the Act for a medicine to be included as a listed or assessed listed medicine in the Register must certify that, among other things:

* the medicine does not contain an ingredient that is not specified in a section 26BB determination; and
* if a section 26BB determination specifies requirements in relation to ingredients being contained in the medicine*—*none of those requirements have been contravened.

Subsection 26BD(1) provides that a person may make an application for a recommendation to be made by the Secretary that the Minister vary a section 26BB determination (“a variation application”). In practice, these applications mainly involve proposals for the approval of new ingredients for use in listed or assessed listed medicines, but an application may also propose a variation to existing requirements for the use of a permitted ingredient.

Subsection 26BD(2) provides that when a variation application is made, the Secretary must carry out an assessment of whether the requirements set out in subsection 26BD(3) have been met in relation to the application. These subsections provide for a preliminary assessment process. An applicant passes preliminary assessment if the Secretary is satisfied, after assessing the application, that the requirements in subsection 26B(3) have been met (subsection 26BD(4)). Under subsection 26BE(3) of the Act, if an application has passed preliminary assessment (and a small number of other steps are met) the Secretary must carry out an evaluation of whether to make the recommendation.

One of the requirements in subsection 26BD(3) is that the application must be accompanied by information of a kind determined under subsection (8) and in a form determined under subsection (9). Subsections 26BD(8) and (9) provide that the Secretary may make legislative instruments determining the kind of information and form of information that must accompany an application under subsection 26BD(1), providing clarity in relation to what the minimum requirements are for supporting information that must accompany a variation application.

**Purpose**

The Determination specifies the kind of information that must accompany a variation application, as well as the form in which that information must be provided. In particular, the Determination provides that a variation application must be:

* accompanied by information of a kind specified in the document titled *Mandatory requirements for an effective application to vary the Permissible Ingredients Determination*’ (Version 1.0, February 2023) published by the TGA (“the Mandatory Requirements Document”); and
* contained in an application dossier, and in a form consistent with the Mandatory Requirements Document and the document titled *General dossier requirements* (Version 1.4, July 2018) published by the TGA.

The Determination is designed to facilitate the effective management of resources by the Department in the evaluation of variation applications, and to create certainty for applicants in relation to the necessary supporting information and form requirements needed to evaluate an application. The information required to accompany an application is necessary to enable the Secretary to undertake a full evaluation of the application in accordance with section 26BE of the Act, and is information that applicants would be expected to have available when they make an application. The data requirements also ensure that sponsors using application categories based on overseas assessment reports will be able to address Australian specific requirements. The form in which the information must be provided is critical to ensuring that the evaluation can be undertaken efficiently.

A preliminary assessment process under section 26BD, and a subsequent evaluation process under section 26BE, involve considerable investment in, and use of, resources. If an inaccurate or deficient application is received, this could cause delay in the processing of other applications. Mandating content and form requirements for variation applications increases efficiency by providing clarity regarding application requirements, streamlining application and evaluation processes, and preventing delays in assessing applications, and is consistent with other therapeutic goods application processes.

The Mandatory Requirements Document provides that an application dossier must provide appropriate information as specified in Appendix A. Appendix A outlines the specific mandatory requirements with respect to the information that must be provided in relation to each of the four application categories. The application categories, being ‘IN1 applications’, ‘IN2 applications’, ‘IN3 applications’, and ‘IN4 applications’, are defined in regulation 2 of the *Therapeutic Goods Regulations 1990*.

The Mandatory Requirements Document also specifies that an application dossier must contain folders that are named and structured corresponding to the core information requirements that are relevant to the application category, as specified in Appendix A to the Mandatory Requirements Document.

The *General dossier requirements* document stipulates requirements that the electronic submission must comply with, including that the text within documents must be searchable and in English, and outlines how the dossier is to be submitted electronically.

**Incorporation by reference**

The Determination incorporates by reference the following documents:

* *Mandatory requirements for an effective application to vary the Permissible Ingredients Determination* (Version 1.0, February 2023); and
* *General dossier requirements* (Version 1.4, July 2018).

These documents are published by the TGA and are freely available on the TGA website at www.tga.gov.au.

Both these documents are incorporated as in force or existing on 1 February 2023, the date of commencement of the Determination, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003* (“the Legislation Act”).

**Consultation**

The Mandatory Requirements Document has been implemented in close consultation with the Complementary and OTC Medicines Regulatory and Technical Consultative Forum (“ComTech”). ComTech is a forum that facilitates consultation between the TGA and representatives from the complementary and OTC medicines industries including Accord Australia, the Association of Therapeutic Goods Consultants, Complementary Medicines Australia, and Consumer Health Products Australia.

ComTech members were first notified of the development of the Mandatory Requirements Document in October 2019. Between September 2020 and September 2022, the TGA engaged with ComTech members to obtain feedback over three iterations of the draft Mandatory Requirements Document. This included five working group sessions held between February and March 2021, where discussions concerning the mandatory requirements were held with ComTech members, and invited industry expert representatives, to refine the document and associated guidance.

The TGA also engaged with other Commonwealth regulators during this period (Food Standards Australia New Zealand, the Australian Industrial Chemicals Introduction Scheme, and the Office of the Gene Technology Regulator), international regulators (Health Sciences Authority of Singapore and Health Canada), the Advisory Committee on Complementary Medicines, and other professional organisations (including the Australian Society for Microbiology) for the purposes of ensuring that specific technical aspects of the data requirements were fit for purpose. This input was collectively used to develop the Mandatory Requirements Document, and associated guidance.

The TGA provided ComTech members with a final draft of the Mandatory Requirements Document in September 2022. The TGA made amendments to incorporate feedback provided by members during the consultation period. Outstanding issues were addressed in a detailed letter from the TGA to all members in September 2022.

The Determination reflects the implementation of recommendations of the Review of Medicines and Medical Devices Regulation (“the MMDR Review”). The Determination is therefore machinery in nature, and the Office of Impact Analysis has previously advised that an impact assessment is not required where an independent review or other mechanism has undertaken a process and analysis equivalent to an impact assessment (OBPR ref 18884).

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

The Determination is compatible with human rights and freedoms recognised or declared under Part 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 and commences on 1 February 2023.

**Attachment A**

**Details of the *Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023* (“the Determination”)*.*

**Section 2 – Commencement**

This section provides that the Determination commences on 1 February 2023.

**Section 3 - Authority**

This section provides that the legislative authority for making the Determination is subsections 26BD(8) and (9) of the *Therapeutic Goods Act 1989* (“the Act”).

**Section 4 – Definitions**

This section provides the definitions of key terms used in the Determination, including ‘Act’ and ‘Therapeutic Goods Administration’. This section also notes that some expressions used in the Determination, including ‘Secretary’, have the same meaning as in the Act.

**Section 5 – Kind of information**

This section provides that, for the purposes of subparagraph 26BD(3)(e)(i) of the Act, an application for a recommendation by the Secretary that the Minister vary a section 26BB determination must be accompanied by the information specified in the document titled *Mandatory requirements for an effective application to vary the Permissible Ingredients Determination* (Version 1.0, February 2023), published by the Therapeutic Goods Administration, as in force or existing on 1 February 2023.

The note to this section indicates that thedocument referred to in this section is published at www.tga.gov.au.

**Section 6 – Form of information**

This section provides that, for the purposes of subparagraph 26BD(3)(e)(ii) of the Act, the information that accompanies an application for a recommendation by the Secretary that the Minister vary a section 26BB determination must be contained in an application dossier, and in a form consistent with the document titled *Mandatory requirements for an effective application to vary the Permissible Ingredients Determination* (Version 1.0, February 2023) and the document titled *General dossier requirements* (Version 1.4, July 2018) published by the Therapeutic Goods Administration, as in force or existing on 1 February 2023.

The note to this section indicates that the documents referred to in this section are published at www.tga.gov.au.

**Attachment B**

**Statement of compatibility with human rights**

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

***Therapeutic Goods (Permissible Ingredients—Information that Must Accompany Application for Variation) Determination 2023***

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**

Subsection 26BD(1) of the Act relevantly provides that a person may make an application to the Secretary for a recommendation by the Secretary that the Minister vary a determination made under section 26BB of the Act, which specifies permissible ingredients that may be included in listed medicines. Subsection 26BD(3) sets out the requirements for such an application, including that the application must be accompanied by information that is of a kind determined under subsection 26BD(8) and in a form determined under subsection 26BD(9). Subsections 26BD(8) and (9) provide that the Secretary may, by legislative instrument, determine a kind of information and a form of information that must accompany such an application.

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*Background*

Subsection 26BB(1) of the Act relevantly provides that the Minister may, by legislative instrument, make a determination specifying ingredients and, for some or all of those ingredients, requirements in relation to those ingredients being contained in a medicine. Under subsections 26BB(2), (2A) and (3) of the Act, such requirements may relate to particular ingredients not being contained in particular medicines, or being contained in particular medicines only in specified circumstances, or to permitted concentrations or total amounts of an ingredient in a medicine.

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Subsection 26BD(2) provides that when a variation application is made, the Secretary must carry out an assessment of whether the requirements set out in subsection 26BD(3) have been met in relation to the application. These subsections provide for a preliminary assessment process. An applicant passes preliminary assessment if the Secretary is satisfied, after assessing the application, that the requirements in subsection 26B(3) have been met (subsection 26BD(4)). Otherwise, the Secretary must refuse the application (subsection 26BD(6)).

One of the requirements in subsection 26BD(3) is that the application must be accompanied by information of a kind determined under subsection (8) and in a form determined under subsection (9). Subsections 26BD(8) and (9) provide that the Secretary may make legislative instruments determining the kind of information and form of information that must accompany an application under subsection 26BD(1), providing clarity in relation to what the minimum requirements are for supporting information that must accompany a variation application.

*Purpose*

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The Determination is designed to facilitate the effective management of resources by the Department in the evaluation of variation applications, and to create certainty for applicants in relation to the necessary supporting information and form requirements needed to evaluate an application. The information required to accompany an application is necessary to enable the Secretary to undertake a full evaluation of the application in accordance with section 26BE of the Act, and is information that applicants would be expected to have available when they make an application. The data requirements also ensure that sponsors using application categories based on overseas assessment reports will be able to address Australian specific requirements. The form in which the information must be provided is critical to ensuring that the evaluation can be undertaken efficiently.

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The Mandatory Requirements Document also specifies that an application dossier must contain folders that are named and structured corresponding to the core information requirements that are relevant to the application category, as specified in Appendix A to the Mandatory Requirements Document.

The *General dossier requirements* document stipulates requirements that the electronic submission must comply with, including that the text within documents must be searchable and in English, and outlines how the dossier is to be submitted electronically.

**Human rights implications**

The Determination engages the right to health in Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

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 takes positive steps to promote the right to health by ensuring that there is sufficient information accompanying an application for a recommendation by the Secretary that the Minister vary a section 26BB determination to enable the application to be processed by the Secretary in an effective and timely manner. The Determination ensures that the process for applying for a recommendation by the Secretary that the Minister vary a section 26BB determination is as efficient, transparent, and reliable as possible.

The effective and timely processing of a variation application will support the timely availability of listed medicines in Australia and support the quality, safety, and efficacy of medicines listed in the Register. This has flow-on benefits for patients and health practitioners through quicker access to important new medicines in Australia.

**Conclusion**

This Determination is compatible with human rights because it supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights.