# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019*

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.

Section 61 of the Act provides that the Secretary may release specified therapeutic goods information to the public, and certain organisations, bodies or authorities, including the World Health Organisation, authorities of the Commonwealth, States or Territories, and national regulatory authorities of other countries with national responsibility for therapeutic goods.

Subsection 61(1) of the Act relevantly provides that therapeutic goods information means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department's functions.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

The *Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019* ("the Specification") is made under subsection 61(5D) of the Act to specify kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The purpose of the Specification is to facilitate the publication of certain therapeutic goods information relating to compliance reviews that are undertaken by the TGA in relation to listed medicines. The Specification also repeals and replaces the *Therapeutic Goods Information (Outcomes of Compliance Reviews of Listed Complementary Medicines) Specification 2012* ("the former Specification").

## Background

Listed medicines are considered to be low risk and are therefore included in the Australian Register of Therapeutic Goods ("the Register") without undergoing pre-market evaluation by the Secretary. In Australia, listed medicines include certain medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, and homoeopathic and aromatherapy preparations.

In the absence of pre-market evaluation, medicines listed under section 26A of the Act are included in the Register on the basis that those goods are certified by an applicant as meeting specified criteria for low risk medicines relating to quality, safety and efficacy. Medicines listed under section 26AE also rely on certification in relation to quality and safety.

The TGA monitors the ongoing quality, safety and efficacy of listed medicines through a program of random and targeted compliance reviews of a proportion of medicines listed in the Register. These compliance reviews are intended to identify instances of non-compliance with important regulatory requirements.

The former Specification facilitated the publication of information relating to listed medicines (other than sunscreens) that were the subject of a compliance review by the TGA, including whether or not, following the completion of the compliance review, the medicine remained listed in the Register or was cancelled by the Secretary.

The Expert Panel Review of Medicines and Medical Device Regulation ("the Review") recommended a number of reforms to increase the information available to consumers to support health decisions, and to improve the transparency of regulatory processes for all stakeholders. In particular, the Review recommended the timely availability of information for consumers relating to listed complementary medicines, specifically whether those medicines have been subject to post-market review, and the timing and outcome of that review (refer to paragraph C of recommendation 49). In accepting this recommendation, the Government noted that the development of a more comprehensive post-market monitoring scheme would enhance consumer protection and complement existing post-market monitoring processes.

Development of a new approach to publishing details of listed medicine compliance reviews commenced in 2018. The approach was developed in consultation with peak industry and consumer representative bodies to underpin increased transparency about the safety and efficacy of listed medicines, consistent with the Government's response to the Review.

This Specification supports the approach to publication by enabling the Secretary to publish certain therapeutic goods information relating to product safety and efficacy aspects from a compliance review of a listed medicine, including:

- the details of the medicine, including name, listing number and relevant sponsor;
- the type of compliance review undertaken by the TGA (random or targeted);
- actions taken by the relevant sponsor or the TGA during the review;
- the outcome of the compliance review;
- issues identified in relation to the safety or efficacy of the medicine during the compliance review, including contraventions of the Act;
- consumer advice regarding the medicine, being recommendations as to whether the medicine is considered safe for continued use, or whether consumers should take any particular action in relation to the medicine;
- where applicable, the grounds for cancellation of the listing of the medicine from the Register and the date of cancellation, being the effective date;
- the date that the outcome of the compliance review was notified to the relevant sponsor, being the date the compliance review was concluded;
- the date that the information was published by the TGA;
- additional information that is relevant to the medicine following the conclusion of the compliance review.

The publication of this information will serve the dual purpose of first aiding consumers in making informed choices about the use of listed medicines, and second promoting industry compliance with legislative requirements.

**Consultation**

A regulation impact statement was not required in relation to the development of the Specification, as the matter of specifying kinds of therapeutic goods information under subsection 61(5D) of the Act is the subject of a standing exemption (OBPR ID 15070). However, extensive consultation was conducted with respect to the approach, and the options for the publication of therapeutic goods information relating to compliance reviews. An initial public consultation on the broad approach for improving transparency about compliance review outcomes took place between September and November 2017.

Further targeted consultation workshops on the structure and implementation of the approach were held throughout 2018, with peak industry bodies (Complementary Medicines Australia ("CMA"), Consumer Healthcare Products Australia and Accord Australasia), certain listed medicine sponsors (including Blackmores, Sanofi, Swisse and Pharmacare) and consumer representatives (Consumers Health Forum of Australia and Choice).

There were regular communications with individual sponsors and key industry associations throughout 2019. An additional consultation workshop was held in August 2019 to address concerns raised by some companies and industry groups and to ensure that the proposed approach to the publication of information is meaningful to consumers.

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

The Specification 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 Specification 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 (Listed Medicines—Compliance Reviews) Specification 2019***

**Section 1 Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019* ("the Specification").

**Section 2 Commencement**

This section provides that the Specification 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 Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act").

**Section 4 Definitions**

This section provides definitions for certain terms used in the Specification, including compliance review, relevant medicine and relevant sponsor. The section also notes that a number of terms have the meaning given in section 3 of the Act, including medicine, Register and Secretary.

**Section 5 Therapeutic goods information**

This section provides that the kinds of therapeutic goods information mentioned in column 2 of the table in Schedule 1, as described in column 3 of the corresponding item, are specified for the purposes of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in the table in Schedule 1 to the Specification.

**Section 6 Repeals**

This section provides that each instrument specified in Schedule 2 to the Specification is repealed. The purpose of this section is to repeal the *Therapeutic Goods Information (Outcomes of Compliance Reviews of Listed Complementary Medicines) Specification 2012*.

**Schedule 1 Specified kinds of therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act.

## Schedule 2 Repeals

This Schedule specifies the *Therapeutic Goods Information (Outcomes of Compliance Reviews of Listed Complementary Medicines) Specification 2012* for the purposes of section 6 of the Specification, with the effect that the whole of this instrument is repealed.

**Attachment B**

## Statement of Compatibility with Human Rights

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

***Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019***

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

The *Therapeutic Goods (Listed Medicines—Compliance Reviews) Specification 2019* ("the instrument") is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act"). The purpose of the instrument is to specify kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act.

The instrument facilitates the publication of certain therapeutic goods information relating to compliance reviews carried out by the Therapeutic Goods Administration ("the TGA") in respect of listed medicines. The instrument also repeals and replaces the *Therapeutic Goods Information (Outcomes of Compliance Reviews of Listed Complementary Medicines) Specification 2012* ("the former instrument").

Listed medicines are considered to be low risk and are therefore included in the Australian Register of Therapeutic Goods ("the Register") without undergoing pre-market evaluation by the Secretary. In Australia, listed medicines include certain medicinal products containing such ingredients as herbs, vitamins, minerals, nutritional supplements, and homoeopathic and aromatherapy preparations.

Medicines that are listed under section 26A of the Act are included in the Register on the basis that the goods are certified by an applicant as meeting specified criteria for low risk medicines relating to quality, safety and efficacy. Medicines listed under section 26AE also rely on certification in relation to quality and safety.

The TGA monitors the ongoing quality, safety and efficacy of listed medicines through a program of random and targeted compliance reviews of a proportion of medicines listed in the Register. These compliance reviews are intended to identify instances of non-compliance with important regulatory requirements.

The former instrument facilitated the publication of information relating to listed medicines (other than sunscreens) that were the subject of a compliance review by the TGA, including whether or not, following the completion of the compliance review, the medicine remained listed in the Register or was cancelled by the Secretary.

In recent years, the Expert Panel Review of Medicines and Medical Device Regulation ("the Review") recommended a number of reforms to increase the information available to consumers to support health decisions, and to improve the transparency of regulatory processes for all stakeholders. In particular, the Review recommended the timely availability

of information for consumers relating to listed complementary medicines, specifically whether those medicines have been subject to post-market review, and the timing and outcome of that review (refer to paragraph C of recommendation 49). In accepting this recommendation, the Government noted that the development of a more comprehensive post-market monitoring scheme would enhance consumer protection and complement existing post-market monitoring processes.

Development of a new approach to publishing details of listed medicine compliance reviews commenced in 2018. The approach was developed in consultation with peak industry and consumer representative bodies to underpin increased transparency about the safety and efficacy of listed medicines, consistent with the Government's response to the Review.

This instrument supports the approach to publication by enabling the Secretary to publish certain therapeutic goods information relating to product safety and efficacy aspects from a compliance review of a listed medicine. The kinds of therapeutic goods information specified under the instrument include details of the relevant listed medicine, details of the compliance review undertaken by the TGA (including whether the review is targeted or random, and the type of information reviewed), the issues identified in relation to the safety or efficacy of the medicine (including contraventions of the Act), consumer advice regarding continued use and required action in relation to the medicine, actions taken during the review and the review outcome.

The publication of therapeutic goods information specified in the instrument is intended to aid consumers in making informed choices about the use of listed medicines, and to promote industry compliance with legislative requirements.

**Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("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 instrument takes positive steps to promote the right to health by helping to ensure the safe and proper use of therapeutic goods that are listed medicines. The instrument seeks to protect and promote the health of all Australians by specifying therapeutic goods information that relates to the compliance reviews undertaken by the TGA in relation to listed medicines, including the outcomes of those reviews.

The publication of therapeutic goods information specified in this instrument will assist consumers in making more informed choices about the use of listed medicines, and act as an appropriate incentive for sponsors of such medicines to improve overall compliance with applicable regulatory requirements.

**Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

**John Skerritt, delegate of the Minister for Health**