

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020

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 (Medicines and Biologicals—Ingredients and Components Information) Specification 2020* (“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 enable publication of, and thereby facilitate better public access to, information relating to ingredients contained in medicines and components of biologicals (“ingredients and components information”) that are included in the Australian Register of Therapeutic Goods (“the Register”).

Background

Allergic diseases are one of the fastest growing public health issues in Australia, with almost 20 per cent of Australians living with a confirmed allergy. These include food, insect and drug allergies, the symptoms of which range from mild to life-threatening anaphylactic reactions. Allergic diseases are increasing in prevalence, complexity and severity, particularly food and drug allergies. Consequently, it is becoming increasingly important for the public to have readily available access to ingredients and components information, which would assist in selecting and using those goods safely and effectively.

Medicines contain both active ingredients and excipients. Active ingredients are therapeutically active components in the final formulation of medicines responsible for the physiological or pharmacological action. The remaining ingredients, known as excipients, are generally used to create the medicine’s dosage form, and to help improve such things as absorption, stability, taste and appearance.

Biologicals are therapeutic goods that comprise, contain or are derived from human cells or human tissues. Biologicals are constituted by active components, as well as any other components added in a manner similar to medicines to assist with such things as absorption, stability, taste and appearance.

Both medicines and biologicals may contain proprietary ingredients. A proprietary ingredient is a formulation, such as a colour, flavour or fragrance, made with a mixture of ingredients prior to being included in the medicine or biological. These ingredient mixes are known as proprietary ingredients because the ingredients are commonly referred to by their trade or proprietary name. Generally, details of proprietary ingredient formulations are considered to be commercially confidential and are not in the public domain.

The TGA currently publishes in the Register the name and amount (where relevant) of the active ingredients or components for all medicines and biologicals. The sponsors of medicines and biologicals also include this information, as well as the presence of any common allergens, on product labels.

Moreover, for prescription medicines, the names of both active ingredients and excipients contained in the medicine are included in the product information for the medicine approved under section 25AA of the Act and the patient information as provided for under regulation 9A of the *Therapeutic Goods Regulations 1990* (“the Regulations”).

However, information about excipients has generally been unavailable for biologicals and non-prescription medicines, unless the sponsor voluntarily publishes that information.

The Specification facilitates the open publication in the Register of certain kinds of therapeutic goods information relating to the ingredients in medicines and components of biologicals.

Specifically, the Specification provides legislative authority for the release of the following information relating to medicines:

- the name and amount of each active ingredient;
- the name of each other ingredient, other than a proprietary colour, proprietary flavour, and proprietary fragrance; and
- the description “colour”, “flavour”, or “fragrance”, as a way of denoting that the medicine contains a proprietary colour, proprietary flavour or proprietary fragrance, without disclosing details of those commercially confidential ingredients.

Similarly, the Specification provides legislative authority for the release of the following information in relation to biologicals:

- the name and amount of each active component;
- the name of each other component, other than a proprietary colour, proprietary flavour, and proprietary fragrance; and
- the description “colour”, “flavour”, or “fragrance”, as a way of denoting that the biological contains a proprietary colour, proprietary flavour or proprietary fragrance, without disclosing details of those commercially confidential ingredients.

These measures ensure that consumers have better access to ingredients and components information, which would help consumers make more informed and safer choices when selecting or using medicines and biologicals. The availability of ingredients and components information would also assist consumers and health practitioners identify when specific ingredients or components may have contributed to an adverse reaction.

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 approaches and options for publication of information relating to ingredients contained in medicines and components of biologicals. Between 29 August and 10 October 2019, the TGA sought submissions on the proposal to increase access to ingredients and components information. Interested parties were able to make submissions by participating in a standard submission process or by completing a short consumer survey.

The TGA received 39 standard submissions from sponsors, manufacturers, ingredient suppliers, industry bodies, government organisations, and consumer and health professional groups and individuals. The TGA also received 402 responses to the consumer survey.

In general, submissions made by consumers and health professionals advocated for the publication of all information relating to ingredients in medicines and components of biologicals included in the Register, including details of proprietary ingredients such as colours, flavours, and fragrances. However, many of the submissions made by the therapeutic goods industry confirmed that, while publishing the names of most excipients and ingredient mixes would not compromise commercial confidentiality, the trade names of proprietary colour, proprietary flavour and proprietary fragrance mixes should remain confidential.

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.

Details of the *Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020* (“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 proprietary colour, proprietary flavour, and proprietary fragrance. The section also notes that a number of terms have the meaning given in section 3 of the Act, including medicine, biological, and Register.

Section 5 Therapeutic goods information

Subsection 5(1) provides that, in relation to a relevant medicine, the kinds of therapeutic goods information mentioned in column 2 of the table in Part 1 of Schedule 1, as described in column 3 of the corresponding item, are specified for the purposes of subsection 61(5C) of the Act.

Subsection 5(2) provides that, in relation to a relevant biological, the kinds of therapeutic goods information mentioned in column 2 of the table in Part 2 of 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, in relation to both relevant medicines and relevant biologicals, therapeutic goods information of the kind set out in the tables in Schedule 1 to the Specification.

Schedule 1 Specified kinds of therapeutic goods information

Part 1 of this Schedule specifies the kinds of therapeutic goods information in relation to a relevant medicine that may be released to the public by the Secretary under subsection 61(5C) of the Act. Part 2 of this Schedule does the same in relation to a relevant biological.

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Medicines and Biologicals—Ingredients and Components Information) Specification 2020

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 (Medicines and Biologicals—Ingredients and Components Information) Specification 2020* (“the instrument”) is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* (“the Act”), 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 purpose of the instrument is to enable publication of, and thereby facilitate better public access to, information relating to ingredients contained in medicines and components of biologicals (“ingredients and components information”) that are included in the Australian Register of Therapeutic Goods (“the Register”).

The measures would ensure the public has better access to ingredients and components information, which would help consumers make more informed and safer choices about medicines and biologicals. The availability of ingredients and components information would also assist consumers and health practitioners identify when specific ingredients or components may have contributed to an adverse reaction.

Specifically, the instrument provides legislative authority for the release of the following information relating to medicines:

- the name and amount of each active ingredient;
- the name of each other ingredient, other than a proprietary colour, proprietary flavour, and proprietary fragrance; and
- the description “colour”, “flavour”, or “fragrance”, as a way of denoting that the medicine contains a proprietary colour, proprietary flavour or proprietary fragrance, without disclosing details of those commercially confidential ingredients.

Similarly, the instrument provides legislative authority for the release of the following information relating to biologicals:

- the name and amount of each active component;
- the name of each other component, other than a proprietary colour, proprietary flavour, and proprietary fragrance; and

- the description “colour”, “flavour”, or “fragrance”, as a way of denoting that the biological contains a proprietary colour, proprietary flavour or proprietary fragrance, without disclosing details of those commercially confidential ingredients.

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 medicines and biologicals. The instrument seeks to protect and promote the health of all Australians by specifying therapeutic goods information in relation to ingredients contained in medicines and components of biologicals, assisting the public and health practitioners to make more informed choices about the use of medicines and biologicals, and to identify when specific ingredients or components may have contributed to an adverse reaction.

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.

Jane Cook, delegate of the Minister for Health