EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Breast Implants Information) 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 relevantly 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.

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

The *Therapeutic Goods (Breast Implants Information) 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 breast implants, mammary implants or tissue expanders.

Background

As part of ongoing work regarding breast implant associated anaplastic large cell lymphoma (BIA-ALCL), the TGA has completed its review and laboratory assessment of textured breast implants on the Australian market. The review was announced on 3 May 2019 and involved both laboratory testing and statistical analysis of supply information and the known cases of BIA-ALCL to estimate the risks associated for each type of implant.

BIA-ALCL usually involves a swelling of the breast, typically 3 to 14 years after the operation to insert the breast implant. This swelling is due to an accumulation of fluid. Less commonly, BIA-ALCL can take the form of a lump in the breast or a lump in the armpit. Although fatalities have been recorded, the vast majority of BIA-ALCL are cured by removal of the implant and the capsule surrounding the implant.

It is a rare condition, with expert opinions estimating the published risk of BIA-ALCL at between 1-in-1,000 and 1-in-10,000.

The TGA has proposed regulatory action, suspension or cancellation under Part 4-6 of the Act, in relation to a number of textured implants. It has also imposed new conditions on including a medical device in the Register under section 41FP of the Act.

The publication of information relating to regulatory action, which the TGA has taken and proposes to take, serves the dual purpose of, first, giving to the public, notably breast implant recipients and medical practitioners, clear information about the relevant breast implants,

mammary implants or tissue expanders subject to that relevant regulatory action. Secondly, it provides transparency on at least the preliminary outcomes from the extensive body of laboratory testing and statistical analysis.

It is anticipated that, should information be disclosed under authority of the Specification it will, in accordance with the authority of this instrument, be sufficient to identify the relevant breast implant device, the sponsor and manufacturer and details of the relevant regulatory action including the date that the decision in relation to the relevant regulatory decision was made.

Consultation

A regulation impact statement was not required in relation to the development of this 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).

There has been no consultation on the terms of the Specification; if the Secretary or her delegate proposes to disclose information under authority of the Specification (in accordance with subsection 61(5C) of the Act), she or her delegate will consult with the persons in relation to whom the disclosure is proposed to be made.

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 Act specifies no conditions that need to be satisfied before the power to make this Specification may be exercised.

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.
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Attachment A

Details of the *Therapeutic Goods (Breast Implants Information) Specification 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Breast Implants Information) Specification 2019* ("the Specification").

Section 2 – Commencement

This section provides that the Specification commences 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 the definitions of certain terms used in the Specification. The section notes that a number of terms have the meaning given in section 3 of the Act, including 'device number' and 'sponsor'. Other terms have been defined for the purposes of the Specification, including 'breast implant device', and 'relevant regulatory action'.

Section 5 – Therapeutic goods information

This section provides that the kinds of therapeutic goods information set out in column 2 of the table in Schedule 1 are specified for the purposes of subsection 61(5C) of the Act. The specified kinds of information are as described in column 3 of the corresponding item in the table. 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.

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.

Statement of Compatibility with Human Rights

This statement is prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Breast Implants Information) 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 (Breast Implants Information) 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 will facilitate the publication of certain therapeutic goods information relating to regulatory action, which the Therapeutic Goods Administration ("the TGA") has taken and proposes to take in relation to relevant breast implants, mammary implants or tissue expanders included in the Australian Register of Therapeutic Goods.

The kinds of therapeutic goods information that is specified include information sufficient to identify the affected therapeutic goods, the sponsor, the manufacturer and the relevant regulatory action.

The publication of information relating to regulatory action, which the TGA has taken and proposes to take, serves the dual purpose of, first, giving to the public, notably breast implant recipients and medical practitioners, clear information about the relevant breast implants, mammary implants or tissue expanders subject to that relevant regulatory action. Secondly, it provides transparency on at least the preliminary outcomes from the extensive body of laboratory testing and associated statistical analysis which the TGA has carried out. It is also intended to promote consumer confidence in the regulation of therapeutic goods.

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. The instrument seeks to protect and promote the health of breast implant recipients by specifying therapeutic goods information in relation to regulatory action, which the TGA has taken and proposes to take in relation to relevant breast implants, mammary implants or tissue expanders. The instrument will enable breast implant recipients and medical

practitioners to be informed of the preliminary outcomes of the TGA's extensive laboratory tests and statistical analysis.

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