**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Australian Breast Device Registry)
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(5AA) relevantly provides that the Secretary may release to a person, body or authority that is specified, or is of a kind specified, under subsection 61(5AB) of the Act, therapeutic goods information of a kind specified under subsection 61(5AB) for a purpose specified under that subsection. Subsection 61(5AB) relevantly provides that, for the purposes of subsection 61(5AA), the Minister may, by legislative instrument, specify a person, body or authority, the kinds of therapeutic goods information and the purposes.

The *Therapeutic Goods (Australian Breast Device Registry) Specification 2019* (“the Specification”) is made under subsection 61(5AB) of the Act to specify kinds of therapeutic goods information that the Secretary may release to the Australian Breast Device Registry (“the ABDR”), and the purposes for which that information may be released, under subsection 61(5AA) of the Act.

The purpose of the Specification is to facilitate the release of specified therapeutic goods information to the ABDR for the specified purposes. The ABDR tracks patient health outcomes, monitors the long term safety and performance of breast devices and benchmarks the quality of surgery involving breast implants, breast tissue expanders and acellular dermal matrices.

**Background**

The ABDR was established in 2015 and is administered by Monash University. Information published by the ABDR explains that it:

* provides progressive reports, using validated data, to key stakeholders such as surgeons, hospitals, and the Department of Health including the TGA;
* helps provide recipients of breast devices with peace of mind that their product is being tracked, and facilitates quicker communication to them in the event of a product recall;
* is the first registry in the world to have the support of all surgical craft groups (the Australian Society of Plastic Surgeons, the [Australasian College of Cosmetic Surgery](http://www.accs.org.au/) and [Breast Surgeons of Australian & New Zealand Inc.)](http://www.breastsurganz.org/about/) to develop and implement a registry;
* is conducted by Monash University’s [School of Public Health & Preventive Medicine](https://www.monash.edu/medicine/sphpm/registries/abdr); and
* is an [opt-out registry](https://www.abdr.org.au/about-us/ethics-and-privacy/) to maximise data representation.

The ABDR collects information about breast devices using a data collection form completed by surgeons at the time of surgery. The objective is to collect data related to **all** surgical procedures involving breast implants, breast tissue expanders and acellular dermal matrices (or similar) undertaken nationally. The ABDR develops datasets that are useful to clinicians, government, industry and academics, including data about device failure rates, complications and revision rates of procedures involving breast devices nationally.

It is estimated that 20,000 women undergo breast device surgery in Australia annually. In most cases, breast device surgery is undertaken for breast augmentation, reconstructive surgery e.g., post mastectomy, and to correct congenital deformities.

There is long-standing worldwide debate regarding the safety of breast devices (breast implants, breast tissue expanders and acellular dermal matrices) and their impact on the health and well-being of recipients. As explained by the ABDR, its establishment facilitates real time knowledge on the safety of the devices and has the potential to significantly improve outcomes for patients with implantable breast devices.

Reports generated using data held by the ABDR may include information on best health outcomes and surgical practice, where treatment gaps may exist and its effect on patient outcomes, and facilitates quality improvement.

The information that would be disclosed to the ABDR under the authority of the Specification is primarily raw sales data per manufacturer for breast implants, tissue expanders and acellular dermal matrices. The exclusive purposes for which the disclosure would be made is to determine the “capture rate” of the ABDR, that is, the number of devices registered with the ABDR as a proportion of those supplied in the Australian market, so that the aggregate capture rate may be published in the ABDR’s annual report. The ABDR will maintain the confidentiality of information specific to identifiable manufacturers; that information will not be published.

**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 section 61 of the Act is the subject of a standing exemption (OBPR ID 15070).

The Australian Breast Device Registry Steering Committee was consulted on and supported the proposal for the release of the specified information to the ABDR, for the specified purpose of determining the ABDR’s capture rate and in order for that rate to be able to be published in the ABDR’s annual report. The Committee membership includes the Monash University’s [School of Public Health & Preventive Medicine](https://www.monash.edu/medicine/sphpm/registries/abdr), [the](http://www.plasticsurgery.org.au/) Department of Health including the TGA, the [Australasian Society of Plastic Surgeons, the Australian College of Cosmetic Surgery](http://www.accs.org.au/), Breast Surgeons of Australia and New Zealand, the Medical Technology Association of Australia, the Consumers Health Forum and the Australian Commission on Safety and Quality in Health Care.

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 instrumentfor 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 (Australian Breast Device Registry) Specification 2019***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Australian Breast Device Registry) 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(5AB) 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 ‘manufacturer’, device number’ and ‘Secretary’. Other terms have been defined for the purposes of the Specification, including ‘ABDR’ and ‘breast device’.

**Section 5 – Release of therapeutic goods information**

This section provides that the kinds of therapeutic goods information set out in column 2 of the table in Schedule 1 to the Specification are specified for the purposes of subsection 61(5AA) of the Act, and may be released to the body specified in column 3, for the purposes specified in column 4 of that table.

**Schedule 1 –Therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information that may be released by the Secretary under subsection 61(5AA) of the Act, the body to whom it may be released, and the purposes for which the information may be used.

**Attachment B**

**Statement of Compatibility with Human Rights**

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

***Therapeutic Goods (Australian Breast Device Registry) 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 (Australian Breast Device Registry) Specification 2019* (“the instrument”) is made under subsection 61(5AB) of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the instrument is to facilitate the release of specified therapeutic goods information to the Australian Breast Device Registry (“the ABDR”) for specified purposes. The ABDR was established in 2015 and is administered by Monash University. The ABDR tracks patient health outcomes, monitors the long term safety and performance of breast devices and benchmarks the quality of surgery involving breast implants, breast tissue expanders and acellular dermal matrices.

The ABDR collects information about breast devices using a data collection form completed by surgeons at the time of surgery. The objective is to collect data related to **all** surgical procedures involving breast implants, breast tissue expanders and acellular dermal matrices (or similar) undertaken nationally. The ABDR develops datasets that are useful to clinicians, government, industry and academics, including data about device failure rates, complications and revision rates of procedures involving breast devices nationally.

The kinds of therapeutic goods information that are specified by the instrument include the product name, classification, device number, manufacturer and raw sales data for breast implants, tissue expanders and acellular dermal matrices, on an annual basis. The instrument makes it clear that the purposes for which that information may be released to the ABDR is for determining the “capture rate” of the ABDR, that is, the number of devices registered with the ABDR as a proportion of those supplied in the Australian market, and for it to publish that information (in aggregate form) in its annual report.

There is long-standing worldwide debate regarding the safety of breast devices (breast implants, breast tissue expanders and acellular dermal matrices) and their impact on the health and well-being of recipients. As explained by the ABDR on its website, its establishment facilitates real time knowledge on the safety of the devices and has the potential to significantly improve outcomes for patients with implantable breast devices.

Reports generated using data in the Registry may include information on best health outcomes and surgical practice, where treatment gaps may exist and its effect on patient outcomes, and facilitates quality improvement.

**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 certain medical devices, being breast implants, acellular dermal matrices and tissue expanders. The instrument seeks to promote and protect the health of breast implant recipients by facilitating the release of information that will assist the ABDR to publish accurate, useful information for the benefit of patients, healthcare practitioners and academics practising in this field of medicine. Manufacturers are not anticipated to be identifiable by the publication.

**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**