VARTA
Victorian Assisted Reproductive Treatment Authority

Victorian Assisted Reproductive Treatment Authority (VARTA)

Compliance Strategy 2024

Aim

The aim of this Compliance Strategy is to set out how the Authority carries out its regulatory and compliance functions effectively, transparently, consistently, proportionately and in a risk-based way that is consistent with its legislative functions and remit.

Objective

This Strategy aims to ensure that VARTA'S regulatory approach is risk-based and that VARTA achieves its regulatory priorities in a way that aligns with its strategic objectives, legislative functions and the guiding principles of the Act.

The Compliance Strategy provides a framework for strategic decision-making in relation to the exercise of VARTA's regulatory and compliance powers and functions under the *Assisted Reproductive Treatment Act 2008* (Vic) (the Act).

To achieve this objective, this Strategy also aligns to VARTA's Strategic Plan where relevant.

Principles to guide the exercise of the Authority's regulatory and compliance role

As set out in VARTA's Strategic Plan, VARTA is:

- ***Independent*** *- We operate as a statutory authority guided by the Act and the Minister for Health's Statement of Expectations.*
- ***Evidence-informed*** *- We gather and analyse current evidence and translate findings to inform our work and operations.*
- ***Collaborative*** *- We work in partnership with those working in ART, health, education, research and legal sectors, and we consult with people with lived experience.*
- ***Inclusive*** *- We are committed to the Charter of Human Rights and Responsibilities Act 2006, and to the protection of the welfare of all people treated through and born from ART.*
- ***Sustainable*** *- We operate as an innovative, responsive and capable organisation.*

We perform our regulatory functions in accordance with the guiding principles set out in section 5 of the Act, which provide that:

> *(a) the welfare and interests of persons born or to be born as a result of treatment procedures are paramount;*
>
> *(b) at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise—*
>
> > *the reproductive capabilities of men and women; or*
> >
> > *children born as a result of treatment procedures;*

(c) children born as the result of the use of donated gametes have a right to information about their genetic parents;

(d) the health and wellbeing of persons undergoing treatment procedures must be protected at all times;

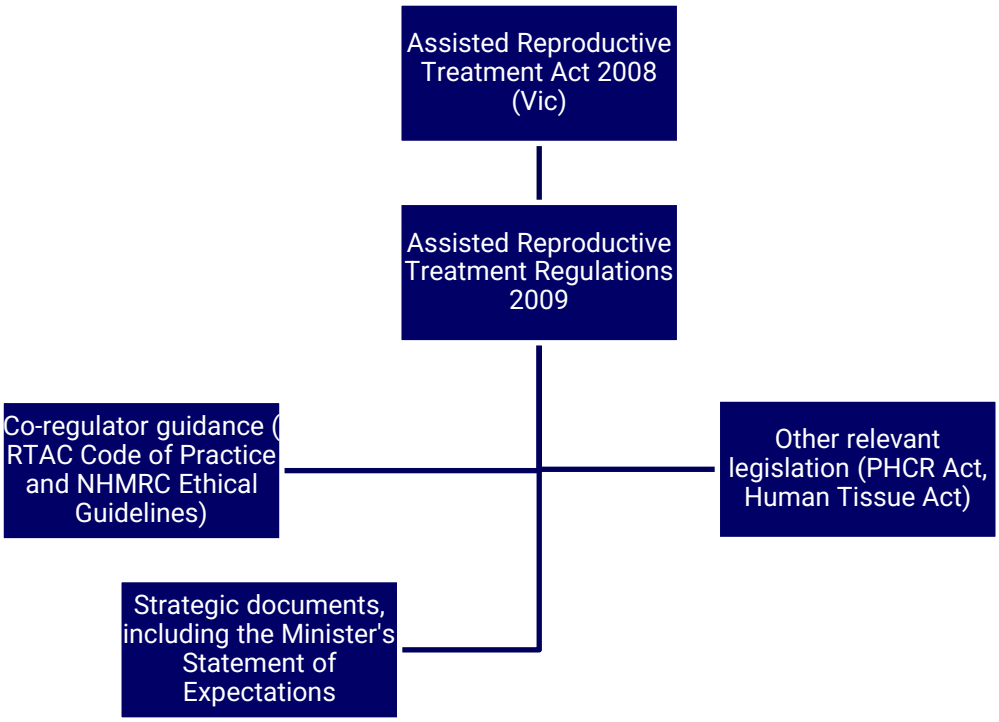
(e) persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

We also strive to be an efficient, transparent, collaborative, risk-based and proportionate regulator. This is what these principles mean to us in carrying out our regulation and compliance functions:

Efficient	We deal with regulation and compliance matters in a timely way and in a way that aligns with our available resources.
Transparent	We work to make sound decisions and provide clear and concise advice. We are open and honest about the reasons for our decisions. We undertake regulatory and compliance processes in accordance with procedural fairness principles where appropriate.
Collaborative	We work with registered ART providers and co-regulators to achieve outcomes.
Risk-based	We take regulatory action where appropriate to reduce and manage identified risks.
Proportionate	We make consistent decisions which respond to relevant circumstances and risks.

Legislative powers and how we use them

VARTA works within a legislative landscape and its statutory powers. The following pieces of legislation and key documents provide the parameters for VARTA's work:



VARTA's regulatory and compliance functions under section 100(1) of the Act include:

- administering the registration of assisted reproductive treatment providers in Victoria;
- monitoring and reporting on treatment outcomes;
- approving the import and export of donor gametes and embryos formed from donor gametes into and out of Victoria.

VARTA does not regulate medical practitioners or clinical practice and cannot receive complaints from the public regarding assisted reproductive treatment providers. VARTA works with co-regulators where appropriate to address matters which may fall into these categories, as set out below.

VARTA has a number of statutory powers which assist us in carrying out its legislative functions:

FUNCTION	SECTION OF THE ACT	POWER
Section 100(1)(g)- approving	Section 36	Approving applications for the import or export of donated gametes and embryos to or from Victoria, including imposing conditions on those approvals

imports and exports	Section 37	Applying exemptions to approvals of donated gametes and embryos Approving applications to move gametes in and out of Victoria with exemptions
Section 100(1)- administering the registration under the Act	Section 74	Approving applications for registration
	Section 75	Imposing conditions on registration of ART providers
	Section 76	Suspension of registration
	Section 77	Immediate suspension of registration
	Section 118	Power to issue Identity Cards to members of the Authority
	Section 119	Power for a member of the Authority to inspect documents of a registered ART provider for the purposes of determining compliance with a registration under the Act

We carry out our functions and use our powers in line with the guiding principles of the Act and the principles set out in this Strategy. VARTA's Board exercises its regulatory and compliance functions, with support and advice from VARTA's staff. VARTA's Conditions for Registration assist VARTA in performing its functions, and also facilitates VARTA making relevant notifications to the Minister for Health.

In addition to our functions and powers, VARTA is required to advise the Minister for Health of any contraventions of the Act or Regulations, or any breaches of an ART provider's conditions of registration, under section 100(2) of the Act. VARTA is also required to notify the Minister for Health of developments in relation to research relating to infertility and treatment for infertility where VARTA believes that they are of major importance or views then with concern.

Key regulatory and compliance priorities for 2024

VARTA has developed regulatory and compliance priorities for 2024, to ensure that it adequate addresses relevant risks and so that it can strategically focus its regulation and compliance resources.

VARTA's regulatory and compliance priorities for 2024 are as follows:

- Enabling efficient and transparent regulatory decision-making through process and communication improvements, including in relation to import and export applications;

- Embed processes and systems to ensure that appropriate data and information can be generated to support the identification of risks and subsequent regulatory decisions.
- Ensuring clinical adverse incidents are consistently reviewed by a clinical expert to ensure that regulatory decision-making is evidence-based and to facilitate referrals to co-regulators where required;
- Consistently record and review adverse incidents submitted by registered ART providers to ensure that trends or breaches can be identified, appropriate investigations are undertaken and notifications to the Minister for Health occur where required; and
- Working collaboratively with registered ART providers to mitigate identified risks, including in relation to breaches of the Act.

Working with co-regulators

Where appropriate, we work with co-regulators, including by making referrals or seeking information or advice. We work with co-regulators in a way that is consistent with the principles set out in this Strategy.

Some key co-regulators that VARTA works with, and how we work with them, are identified below:

The Reproductive Technology Accreditation Committee (RTAC) and the Fertility Society of Australia (FSA)	We liaise with RTAC and the FSA in relation to matters regarding the RTAC Code of Practice and matters relating to registered ART provider accreditation and registration.
Victorian health complaints commissioner	When appropriate, we refer members of the public who wish to make a complaint about treatment received at a registered art provider to the Health Complaints Commissioner.
Australian Health Practitioner Regulation Agency (AHPRA)	When an adverse incident or other report raises a concern about a registered health practitioner or an individual claiming to be a health practitioner, we refer the concern to AHPRA as appropriate.
The Patient Review Panel (PRP)	When we receive a request or query about applications for pre-implantation genetic diagnosis (PGD)(or equivalent) to select the sex of a child, posthumous use gametes, extended storage of gametes, surrogacy and refusal of treatment by an ART, we refer that query to the PRP.
Safer Care Victoria	We liaise with Safer Care Victorian in relation to the management of adverse incidents which may also be sentinel events.
National Health and Medical Research Council (NHMRC)	We consider resources and guidelines around ART nationally and access to research in emerging health issues produced by the NHMRC.

The Department of Health, Victoria	When we receive queries about advertising for donors or policy matters, we refer them to the Department of Health.