Regulator Plan

Victorian Assisted Reproductive Treatment Authority

October 2019

This is the second version of the Victorian Assisted Reproductive Treatment Authority Regulator Plan. It was approved by the Authority on 23 October 2019.

Comments and feedback are welcomed.

To receive this publication in an accessible format phone (03) 8601 5250, or email varta@varta.org.au.

Contents

Introduction 4
Principles 5

Regulator's context 7
Regulatory framework 7
Regulatory activities 9
Complementary activities 9

Defining outcomes 10

Risk overview 13
Identified risks 13
Assessing and treating risks 14
Regulatory tools 19
Regulatory Instruments 20

Monitoring outcomes 21
Our contribution story 21
Our direct indicators 22

Stakeholder engagement 23
Communication activities 23

Glossary 26

Introduction

The Victorian Assisted Reproductive Treatment Authority (the Authority) is a statutory authority established by Part 10 of the *Assisted Reproductive Treatment Act* 2008 (the ART Act) and is funded by the Victorian Department of Health and Human Services (department).

The purpose of this Regulator Plan is to clarify the Authority's regulatory role and outline its regulatory approach, in line with the regulatory practice principles set out in this plan and the conceptual framework in the department's *Better regulatory practice framework.*

These principles guide the work of the Authority in undertaking its regulatory functions and aim to provide the public and Victorian assisted reproductive treatment providers with clear information on the objectives and decision-making principles that apply in carrying out these functions.

The structure of the Regulator Plan document includes:

- defining outcomes
- risk overview
- monitoring outcomes
- stakeholder engagement

This plan is effective from 19 September 2019. It will then be reviewed and updated:

- every two years - in line with the requirement for Victorian ministers to develop and re-issue a ministerial statement of expectations every two years; or
- where key legislative or policy changes are made that will impact on regulatory functions and the currency of the Regulator Plan.

Feedback regarding the plan can be sent to varta@varta.org.au.

Principles

In order to achieve its outcomes, the Authority's approach to its regulatory role and functions is informed by better regulatory practice principles, including those adopted in Victoria, interstate and internationally. In particular, the Authority takes a systematic, risk-based regulatory approach to minimise the risk of harm by working to protect the health and wellbeing of people undergoing treatment procedures and promote the welfare and interests of children born from such procedures as paramount. Endeavouring to support and optimise regulatory compliance by registered assisted reproductive treatment (ART) providers assists to prevent or minimise harm to those involved in treatment procedures, optimises the health and welfare of children born, and promotes the guiding principles of the ART Act.

The Authority applies the following regulatory practice principles in administering and complying with the ART Act, which defines the scope of the Authority's work and its functions. The principles have been informed by the principles set out in the department's *Better Regulatory Practice Framework*.

The Authority also considers the guiding principles of the ART Act wherever appropriate in implementing regulatory practice principles and performing its functions under the ART Act.

Table 1: Regulatory practice principles

Principle	Commitment
Collaborative	The Authority works with the co-regulators and other agencies to maximise effectiveness and minimise regulatory burden, particularly where different regulatory regimes intersect with the Authority's activities. It works cooperatively and collaboratively with stakeholders, including interstate counterparts and those representing various client groups in the Victorian community. The Authority actively looks for opportunities to partner, collaborate and share information with others in order to improve effectiveness and reduce duplication.
Consistent	The Authority works to provide a consistent experience for key stakeholders and the community. Regulatory responses should be predictable and where possible standardised, following clear processes and delivering consistent results. This ensures that individuals/organisations are treated fairly, and the Authority is objective in its decision-making. The Authority aims to ensure that similar circumstances and incidents lead to comparable outcomes.
Efficient	The Authority allocates resources in a way that aims to most efficiently achieve outcomes. This includes minimising unnecessary administrative burden and any adverse impacts of regulatory actions on registered ART providers to a level that is justifiable to achieve regulatory outcomes and meet community expectations.
Information-led	The Authority analyses incoming information, data and evidence in assessing risks and measuring compliance. This allows the Authority to be accurate in its risk assessments and compliance activities. The Authority also makes decisions, both regulatory and administrative, using comprehensive, accurate and current information and evidence. The Authority maintains independence and impartiality in carrying out its activities and functions and collects intelligence and data independently when appropriate.
Outcomes-focused	Processes and decision-making are driven by outcomes. Progress against outcomes is measured to ensure continuous improvement. The Authority monitors and evaluates its work to improve performance, value and output. It prioritises the wellbeing of those who access ART and children born as a result of ART.

Proportionate	The Authority's work will be proportionate to the risk being addressed. The principle of proportionality will guide the Authority's decisions in relation to the level of resources assigned to manage a particular risk, the regulatory tools used and enforcement activities.
Risk-based	The Authority aims to be proactive and responsive in identifying, assessing and responding to risk by prioritising and targeting resources toward specific groups or behaviours that pose the greatest risk to health and wellbeing of the public.
Transparent	Wherever possible and in the public interest, the Authority is open in its decision-making and processes, recording decisions appropriately, including the justification for decisions. It aims to assist registered ART providers and, where applicable, the public, to understand the decision-making processes, areas of focus and performance. As required by the ART Act, it follows standard reporting requirements, enabling the Minister for Health and the department to monitor the performance of its activities.

Regulator's context

Regulatory framework

The overarching purpose of the Authority is to promote and protect the health and wellbeing of all Victorians involved in assisted reproductive treatments (ART) and children to be born. The other key purposes of the Authority include the regulation of access to information about donor treatment procedures and the determination of applications to import or export donor gametes (sperm or oocyte) or embryos produced from donor gametes. The legislation administered by the Authority to achieve these outcomes is the *Assisted Reproductive Treatment Act* 2008 (the ART Act) and the *Assisted Reproductive Treatment Regulations 2009* (the Regulations).

Whilst the legislation is largely administered by the Authority, the Patient Review Panel (PRP), located within the department, administers the parts of the ART Act dealing with applications for surrogacy arrangements, posthumous use of gametes/embryos, cases where a 'presumption against treatment' exists or treatment does not meet criteria as well as issues around the storage of gametes/embryos. This document does not cover the functions of the PRP.

The Authority must, in administering the ART Act and carrying out its functions under the ART Act, give effect to the following guiding principles, as set out in section 5 of the ART Act:

- the welfare and interests of persons born or to be born as a result of treatment procedures are paramount
- at no time should the use of treatment procedures be for the purpose of exploiting, in trade or otherwise:
    - the reproductive capabilities of men or women
    - children born as a result of treatment procedures.
- children born as a result of the use of donated gametes have a right to information about their genetic parents
- the health and wellbeing of persons undergoing treatment procedures must be protected at all times
- persons seeking to undergo treatment procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion.

The Authority's key regulatory role is the registration of Victorian ART providers to operate under the requirements in the Act, Regulations and the *Conditions for Registration.* The Authority monitors and reports to the Minister for Health on registered ART providers compliance with Act, Regulations and *Conditions for Registration.*

The Authority's key regulatory tool is the *Conditions for Registration* which are imposed on each registered ART provider and amended from time to time to address emerging risks that are in the public interest and not inconsistent with any conditions in the RTAC Code of Practice (co-regulator).

The Authority monitors registered ART providers' compliance with the ART Act through communication and collaboration. Where non-compliance occurs, the Authority works with registered ART providers so that they adequately identify and address the cause of non-compliance and minimise further risk.

The Authority also focuses on risks associated with consumer decision-making by supporting research and communication activities that aim to provide independent, evidence-based information for consumers and the broader community in relation to ART.

Regulation is developed and enforced transparently to promote the sharing of information and learnings. Where conditions are imposed on the registration of ART providers in the public interest under the ART Act, these are published on the Authority's website at www.varta.org.au.

The Authority publishes information on its activities in a way that is easily understandable, clearly shows performance and ensures it can be held to account. In addition to making information available, the Authority

recognises the importance of actively engaging with stakeholders and informing them of decisions and regulatory activities.

Groups we rely on to undertake our regulatory function

The Authority works with several co-regulators who have complementary objectives or functions as well as stakeholders. The Authority carries out its regulatory functions with the cooperation and assistance of the following key groups:

- Reproductive Technology Accreditation Committee (RTAC) – RTAC is a subcommittee of the board of the Fertility Society of Australia and is charged with the responsibility of setting standards for the performance of ART through an audited Code of Practice and the granting of licences to practice ART within Australia. The Authority and RTAC cooperate and share information in a number of contexts, including consultation on the Code of Practice and investigations
- Health Complaints Commissioner (HCC) – HCC resolves complaints about healthcare and the handling of health information in Victoria. The Authority and the HCC may liaise in relation to an inquiry or any systemic issues or trends identified through the receipt of complaints by the HCC.
- Australian Health Practitioner Regulation Agency (AHPRA) – AHPRA is responsible for regulating registered health practitioners. The Authority and AHPRA communicate regarding issues that impact on both entities, such as concerns about the professional conduct of a registered health practitioner who practices at a registered ART provider or misleading advertising practices
- Australian Competition and Consumer Commission (ACCC) – the ACCC enforces the *Competition and Consumer Act 2010* (Cth). The Authority may communicate with the ACCC in relation to any concerns about misleading advertising by registered ART providers
- Patient Review Panel (PRP) – the PRP functions are noted above. The PRP and the Authority communicate about issues where approval functions may intersect, such as import or export approval decisions that involve surrogacy arrangements and investigations into potential breaches of the ART Act.
- Private Hospitals Unit within the department that approves the accreditation of private hospital facilities or day procedure centres
- National Health and Medical Research Council (NHMRC) - the NHMRC funds health and medical research and provides advice and guidelines in relation to health standards. The Authority and the NHMRC liaise in relation to the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth), particularly on the issue of commercial trading in gametes and embryos.

Regulatory activities

The Authority undertakes the following key regulatory activities:

- **Supporting compliance:** providing information and guidance to registered ART providers on compliance with the Act, Regulations and *Conditions for Registration* through formal and informal meetings. Dissemination of guidance material to facilitate the making of import and import approval applications.
- **Monitoring compliance:** investigating adverse incidents, actual or potential breaches of the ART Act and/or *Conditions for Registration.* Reviewing RTAC audits, other specific audits and progress on the implementation of agreed corrective actions.
- **Broader monitoring** of programs and activities under the ART Act through regular meetings with clinic representatives, convening of the Advisory Panel and intelligence gathering at public and industry forums.
- **Responsive intervention and enforcement:** imposing special *Conditions for Registration* on a registered ART provider, referring matters to co-regulators for investigation and reporting to the Minister for Health on investigation outcomes.
- **Determination** of import and export applications of donor gametes and embryos formed from donor gametes into or from Victoria.

Complementary activities

In addition to the above regulatory activities, the Authority also has responsibility for the following complementary activities which support the ART Act's outcomes:

- managing the Central and Voluntary Registers
- providing counselling and support services for people born as a result of donor treatment procedures, their parents and donors, including as part of the management of the donor registers
- providing public education in relation to treatment procedures and the best interests of children born as a result of treatment procedures
- undertaking community consultation about matters related to the ART Act
- monitoring programs and activities carried out under the ART Act
- monitoring programs and activities relating to the causes and prevention of infertility
- monitoring programs and procedures relating to ART procedures carried out outside of Victoria
- promoting research into the causes and prevention of infertility.

Example of a non-regulatory activity which is a priority for the Authority:

- as lead partner of the Fertility Coalition (also comprising Healthy Male (formerly Andrology Australia), Monash University, Jean Hailes for Women's Health, The Robinson Research Institute), the management of the national *Your Fertility* health promotion program, funded by the Commonwealth Department of Health and the department. This program undertakes a range of public education activities aimed at improving awareness of fertility issues

Example of an activity that intersects with regulatory activities which is a priority for the Authority:

- provision of information and promotion of public awareness about specific aspects of ART treatments, including IVF, Intracytoplasmic Sperm Injection (ICSI), pre-implantation genetic testing (PGT) and the use of adjuvant therapies within a program of ART treatment.

Defining outcomes

The objectives outlined in this section include both the Authority's regulatory and complementary activities, which are carried out cohesively to ensure that the outcomes are achieved in a comprehensive way. The Authority's contribution is limited to the scope of its powers and functions under the ART Act and acknowledges that other factors and bodies also contribute to these outcomes.

Regulatory scheme	Outcome 1 - Regulation of ART
Outcome the Authority contributes to	Protecting the health, safety and wellbeing of ART patients, donors, surrogates and children to be born by:
Objectives	• mandating, in the *Conditions for Registration,* that the Authority is notified of any adverse incidents (including potential or actual breaches of the ART Act, Regulations or the *Conditions for Registration* and incidents which involve harm to a patient's health/wellbeing), and any new treatment procedures that the ART provider is proposing to use • investigating adverse incidents and, where warranted, imposing additional *Conditions for Registration* • collecting information about current issues in the ART sector, including issues related to person-centred care, to inform the Authority's strategic planning and the development of guidance for ART providers • providing information and education to the public regarding fertility issues, ART treatments, donor treatment, and surrogacy arrangements

Regulatory scheme	Outcome 2 - Regulation of ART
Outcome the Authority contributes to	Supporting the right of donor-conceived people to access information about their donors or relatives, and protecting their welfare and interests by:
Objectives	• managing the Central and Voluntary Registers and ongoing monitoring and amendments to the Registers to ensure it is up-to-date and accurate • collecting information from the ART providers about the birth of donor-conceived people, including the name of the person born as a result of donor treatment, the name of the donor, and the name of the person receiving treatment and the person's partner • collecting information from doctors about the birth of people born as a result of artificial insemination, including the name of the person born as a result of artificial insemination, the name of the sperm donor, and the name of the person receiving treatment and the person's partner • providing information and support sessions to people about the Central Register, and how to make an application under the ART Act to the Central Register for both identifying and non-identifying information about their donors

	• providing information and support sessions to people about the Voluntary Register, and how to voluntarily record information about themselves and their wishes • providing information and support to people about how to lodge an application for donor-linking and potentially connect with their donors, siblings and the person and/or the person's partner who have undergone donor treatment procedures • processing applications for the import and export of donor gametes and embryos consistently, requiring that identifying information about donors relevant to the applications is available to be placed on the Central Register • providing appropriate counselling and information to donor-conceived people on their rights under the ART Act • providing support and information to parents of donor-conceived people to tell their children about their conception • monitoring the 10 women limit for treatment using a donor.

Regulatory scheme	**Outcome 3 - Regulation of ART**
Outcome the Authority contributes to	Reducing the risks of exploitation of the reproductive capabilities of intending parents, donors and surrogates by:
Objectives	• providing information and education on fertility and issues related to assisted reproductive treatment, thereby reducing the risks of misinformation • requiring, when processing applications for import and export, that a declaration, stating that the donation and surrogacy arrangement (if relevant) are both altruistic is provided with the application • mandating, in the *Conditions for Registration*, that ART providers notify the Authority if they are proposing to utilise a new procedure or treatment • encouraging intending parents to consider local donors and surrogates, rather than those living overseas, through online, print and verbal information • providing information about how to advertise for egg donors in accordance with Victorian law • providing information on ART adjuvant therapies (add on), egg freezing and the unexplained infertility interactive tool.

Regulatory scheme	Outcome 4 - Regulation of ART
Outcome the Authority contributes to	Optimising outcomes for ART patients and preventing the unnecessary use of ART by Victorians through:
Objectives	• notifying the department and Minister of any developments that the Authority considers of importance or concern in research relating to ART • actively monitoring nationally and internationally emerging trends in reproductive medicine and liaising with the ART industry in relation to this • using contemporary evidence-based information to regularly update information resources, web-based tools and presentation materials • provide information about ART outcomes including birth rates for different age groups, in a neutral way.

Risk overview

This section includes a risk assessment and risk management strategy, which identifies a small number of key risks to the Authority's outcomes.

Identified risks

The key risks that the Authority has identified are as follows (in no particular order):

1. an increasingly diverse and expanding industry has brought rapid developments in ART. These changes have brought benefits and risks to patients. Uniquely among health services, ART leads to the creation of human lives, and involves inherent risks to the individual undergoing treatment. Some risks such as ovarian hyperstimulation syndrome (OHSS) and incidents that impact on eggs, sperm and embryos are uniquely associated with ART procedures, with potential impact on patients and children to be born
2. there is a clear information and knowledge gap regarding ART treatments between healthcare professionals and patients, with patients reliant on clinics to provide adequate information for them to make informed choices. There is a risk that people are provided with inadequate or inconsistent information regarding the costs, success rates, and the evidence in relation to current or emerging treatments
3. the shortage of donated sperm and eggs in Victoria has resulted in some individuals seeking to use imported gametes or ART treatments interstate or overseas. There is a risk that donors, surrogates and people who require donated gametes or embryos may be subject to exploitation and/or detrimental effects on their emotional or mental health

Assessing and treating risks

The Authority focuses greater effort and resources on risks with an extreme or high rating. Each risk is assessed against the risk matrix (shown below) and given a risk rating.

		Increasing likelihood				
Increasing consequence	**Overall risk rating**	Rare	Unlikely	Possible	Likely	Almost certain
	Extreme	Medium	High	Extreme	Extreme	Extreme
	Major	Medium	Medium	High	High	Extreme
	Moderate	Low	Medium	Medium	High	High
	Minor	Low	Low	Medium	Medium	Medium
	Insignificant	Low	Low	Low	Medium	Medium

Risk #1	**Likelihood: likely**	**Consequence: major**	**Rating: high**

An increasingly diverse and expanding industry has brought rapid developments in ART. These changes have brought benefits and risks to patients. Uniquely among health services, ART leads to the creation of human lives, and involves inherent risks to the individual undergoing treatment. Some risks such as ovarian hyperstimulation syndrome (OHSS) and incidents that impact on eggs, sperm and embryos are uniquely associated with ART procedures, with potential impact on patients and children to be born.

Extent of the risk: HIGH

This risk has been assessed as **high (possible likelihood and moderate to major consequence).**

The reasoning for this assessment is as follows:

Likelihood- likely:

- registered ART providers have reported 80 adverse incident reports to the Authority in the last financial year (58 clinical and 22 scientific incidents reported)

Consequence- major:

- the consequence may be harm to patients and/or children born
- potential legislative non-compliance and adverse impact on industry reputation and public confidence.

Ongoing controls

- monitor activities of ART providers and identify risks as they emerge in a proactive and responsive manner
- investigate reported adverse incidents, identify underlying causes and, where appropriate, advise on and monitor corrective actions taken by ART providers
- meet with Designated Officers annually to discuss any challenges in relation to legislative compliance
- provide guidance to ART providers and maintenance of key relationships with ART provider staff
- utilise Advisory Panel to bring issues to the attention of the Authority
- ensure ART providers submit the attestations required as part of the *Conditions for Registration*

Planned changes in controls for 2019-21

- develop guidance for reporting in relation to reporting requirements, including requirements for the reporting of adverse events, and the use of adjuvant therapies
- review and continuously improve procedures relating to the investigation of adverse incidents
- review of the *Conditions for Registration* annually, including the introduction of new regulatory measures imposed in the public interest
- consult and communicate with ART providers and other stakeholders about how compliance systems can support quality person-centred care, developing guidelines, drawing on RTAC technical bulletins, tailored to the Victorian context
- increased communication and collaboration with RTAC to enhance audits in areas of reported adverse incidents, including legislative non-compliance
- increased collaboration with co-regulators including the Health Complaints Commission and AHPRA

Risk #2	**Likelihood: possible**	**Consequence: moderate**	**Rating: medium**
There is a clear information and knowledge gap regarding ART treatments between healthcare professionals and patients, with patients reliant on clinics to provide adequate information for them to make informed choices. There is a risk that people are provided with inadequate or inconsistent information regarding the costs, success rates, and the evidence in relation to current or emerging treatments			

Extent of the risk: MEDIUM

This risk has been assessed as **medium (possible likelihood and moderate consequence).**

The reasoning for this assessment is as follows:

Likelihood- possible:

- increased use of targeted online marketing strategies and social media by ART services can result in potentially misleading information including testimonials
- the arrival of new providers in the market with increasing competition to provide ART services has also seen a significant increase in marketing and advertising of services
- unrealistic expectation of people about their own fertility may lead them to push for additional services and treatments, even where there is little evidence of their efficacy and/or safety, and where there may be a risk of harm
- sharing of non-professional information and support between peer support networks, friends and family can lead to potentially inaccurate and/or misleading information.

Consequence- moderate:

- inaccurate or misleading information can result in harm to individuals, and potentially children born, if they make inappropriate or unnecessary treatment decisions or suffer emotionally when expectations are not met.

Ongoing controls

- requiring, in the *Conditions for Registration*, that ART providers attest that they are compliant with the advertising provisions of the *Health Practitioner Regulation National Law (Victoria) Act 2009*
- promote information published by the Authority about success rates, costs and adjuvant therapies, including providing questions patients can ask their doctors
- monitor the information published by ART providers in relation to their success rates, costs and adjuvant therapies, alerting ART providers to enable a change to practices.

Planned changes in controls for 2019-21

- develop guidance for the public reporting of treatment costs and success rates to help people to make more informed choices about providers and make meaningful comparisons
- develop and promote web-based information published by the Authority on cumulative IVF success rates and adjuvant therapies
- consider referrals to AHPRA where the Authority believes that an ART provider's public information may breach the advertising provisions of the *Health Practitioner Regulation National Law (Victoria) Act 2009,* if an ART provider is not amenable to making changes.
- Consult and collaborate with ART providers and community organisations to identify needs, to promote existing resources and expand multiculturally appropriate information available to ART service users.

Risk #3	Likelihood: likely	Consequence: major	Rating: high
The shortage of donated sperm and eggs in Victoria has resulted in some individuals seeking to use imported gametes or seek ART treatment interstate or overseas. There is a risk that donors and surrogates may be subject to exploitation in some countries with less regulatory oversight. Less rigorous regulation and processes abroad may also result in greater risk to the physical, emotional and mental health of Victorians receiving treatment and their babies.			

Extent of the risk: HIGH

This risk has been assessed as **high (likely likelihood and major consequence).**

The reasoning for this assessment is as follows:

Likelihood- likely:

- ongoing and increasing demand for donated gametes in Victoria
- lack of public awareness of gamete donation issues
- donor conception and surrogacy services in many countries remain largely unregulated
- the risk of exploitation can be even greater where people travel overseas to seek treatments
- the nature of these activities means that it is not possible to quantify the extent of this issue

Consequence- major:

- increased exposure and risk of exploitation of human reproductive capacities of intended parents, donors and surrogates in some environments with less regulatory oversight
- children born as a result of donor treatment or surrogacy arrangement overseas may not have access to information about their donor and surrogacy conception

Ongoing controls

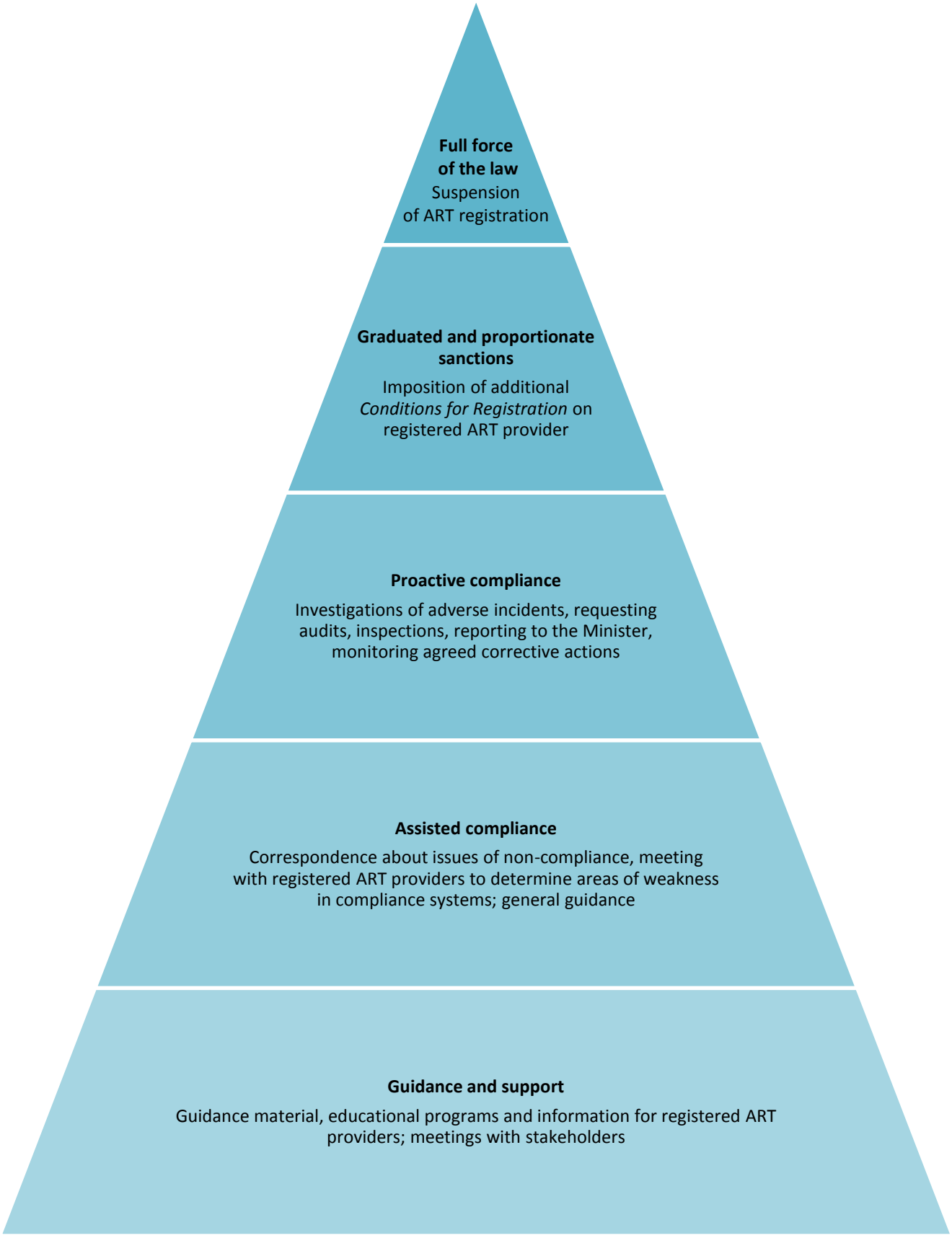
- provide information to the public about gamete donation in Victoria
- provide information and support sessions to help people make an informed decision about whether or not to become a local gamete donor
- provide information about the benefits of using a local donor on the Authority's website, via printed resources and through general enquiries
- consider the guiding principles of the ART Act when considering whether to approve an application for the import or export of donated gametes or embryos produced using donated gametes
- require identifying details of donors to be available for the Central Register as a condition for the approval of donor gametes or embryos containing donor gametes and monitor compliance with this requirement through the management of the Central Register
- encourage ART clinics to recruit a high proportion of local donors

Planned changes in controls for 2019-21

- review the Authority's *Guidelines for the import and export of donor sperm, eggs and embryos produced using donor sperm and/or eggs* in light of the increasing use of overseas gametes
- review public education information and initiatives about donating, and the risks associated with informal donation arrangements in Victoria and anonymous donation arrangements overseas
- consider new measures and ways to support the clinics to recruit locally

Regulatory tools

The full suite of tools available to the Authority in its regulatory role can be illustrated as:



Regulatory Instruments

Conditions for Registration

The Authority has imposed *Conditions for Registration* on all registered ART providers, considering the imposition of these conditions to be necessary and in the public interest. These conditions are consistent with those imposed by RTAC on ART providers' accreditations. The *Conditions of Registration* are designed to:

- require ART providers report to the Authority on adverse incidents that involve harm to a patient's health/wellbeing
- encourage and monitor levels of compliance within the ART providers' systems and processes
- allow the Authority to monitor an ART providers' accreditation and compliance with the RTAC Code of Practice, as well as any significant developments in ART

The Authority believes that the *Conditions for Registration* are in the public interest, as they reinforce the guiding principles of the ART Act and allow the Authority to monitor the ART sector's prioritisation of the interests of patients, donors and the children born as a result of ART treatment.

The Authority has also imposed special *Conditions for Registration* on particular ART providers as tailored regulatory responses to risks identified in the context of an investigation. These special conditions have generally been imposed for a time-limited period. The Authority notifies the Minister for Health when general and special conditions are imposed and publishes all current versions of the *Conditions for Registration* on its website.

If the Authority believes that an ART provider has contravened the *Conditions for Registration*, or if there are other reasonable grounds, the Authority may also suspend the ART provider's registration.

Guidelines for the import and export of donor sperm, donor eggs and embryos produced using donor sperm and/or eggs

The Authority has developed *Guidelines for the import and export of donor sperm, donor eggs and embryos produced using donor sperm and/or eggs* (the Guidelines) in order to set out the considerations which the Authority believes to be relevant in making a decision in relation to an application for import or export.

The guidelines are publicly available, enabling the Authority to explain the requirements that must be met by an application to import or export, and any additional considerations that the Authority believes to be relevant, given the guiding principles of the ART Act.

This document therefore provides the public and registered ART providers with information about the Authority's approval function in relation to imports and exports and insight into the way in which the Authority exercises that regulatory function. The Authority believes that this transparency is crucial, especially given that individuals who make applications to import or export may not be aware of the nature and extent of the Authority's power, or what types of considerations will be relevant.

Monitoring outcomes

In this section, a small number of indicators are outlined that can be used to guide the Authority's activities and evaluate their effectiveness. To the extent possible, these indicators demonstrate the contributions to the outcomes that the Authority is trying to achieve, rather than simply the activities that are being undertaken.

Our contribution story

The Authority contributes to the broader world of ART in a number of ways, outside the purview of its regulatory role.

The Authority contributes by engaging with stakeholders, such as the registered ART clinics and advisory groups, to educate them in relation to changes in the ART landscape, such as legislative amendments, risks to compliance or broader issues in ART.

The Authority also provides independent, evidence-based information for consumers on a number of issues, including how to interpret IVF success rates, the possible health effects of IVF, and what consumers should think about before using a donor or surrogate.

The Authority supports the donor-conceived community and donors, as well as working towards increasing openness in relation to donor conception. Initiatives such as work on the History of Donor Conception Records Project, running support groups and publishing resources to help parents tell a child that they are donor-conceived are some of the ways the Authority pursues this work.

The Authority contributes overall to the promotion of the welfare of all parties involved in donor conception, including donor-conceived people, parents and donors. The Authority recognises the importance of transparency and openness in relation to donor conception and issues surrounding ART more generally.

Our direct indicators

The Authority's success in meeting its objectives and outcomes is measured through a number of indicators as outlined below.

Indicator	Target 2016-17	2016-17 actual	Target 2017-18	2017-18 actual
Annual review of the *Conditions for Registration* (Outcome 1)	Annual review and publication	Annual review and publication	Annual review and publication	Conditions for Registration reviewed in early 2018 and published on VARTA website June 2018
Processing applications for import and export of donated gametes and embryos produced using donated gametes within six weeks of receiving all required information (Outcome 2)	90%	94%	95%	100%
Applications for registration as an ART provider processed within two weeks of receiving all required information (Outcome 1)	100%	Not applicable- no applications received	100%	100% (applications for registration by Genea and Number 1 Fertility for two sites
Audit of all registered ART providers' websites conducted annually in relation to advertising and success rates by the end of each financial year (Outcome ?)	100%	100%	100%	100% (an audit conducted in early 2018 revealed some improvement in the way registered ART providers report success rates on their websites).

Stakeholder engagement

Communication activities

The Authority communicates with a number of stakeholders through formal and informal discussions, consultation and partnerships. The Authority uses a number of mechanisms to successfully communicate with stakeholders, including the Authority's website, newsletter, printed resources, social media and presentations.

The following table outlines the key stakeholders and describes how they are to be engaged on an ongoing basis.

In addition to communicating with the stakeholders listed below, the Authority also reports to the Minister for Health. The Authority prepares an annual report to the Minister, provides information relating to potential or actual breaches of the Act or Regulators, and provides ad-hoc advice to the Minister on significant ART-related matters. The Authority meets with the Minister or her office at least annually.

The Authority also liaises with the department, as well as the Deputy Secretary and Secretary of the department to discuss regulatory and policy matters.

Stakeholder	Type	Actions
Those considering using or currently using ART treatments, and children to be born		• provision of clear and impartial information to all affected by fertility treatment through website and media opportunities • support in navigating access to information about donor treatments • consultation with consumers regarding their need for communication about ART including any add on treatments.
Those people of reproductive age and children born from the use of ART		• provision of clear and impartial information about how to optimise the chance of conception and a healthy pregnancy and baby • provision of clear and impartial information about the health of children born through ART • provision of clear information about the donor conception registers.

Stakeholder	Type	Actions
Registered ART providers	Regulated entity	• liaise and meet with designated officers and other key personnel at least annually, encourage them to bring any issues associated with the Act to the Authority's attention • conduct roundtable discussions regarding issues related to ART with designated officers and other key personnel when required • communicate in writing with designated officers when required regarding issues of compliance, registration and data provision • liaise with key personnel within registered ART providers annually for the development of public education resources, and promote relevant Authority resources • liaise with key personnel to ensure registration details for registered ART providers remain current
Reproductive Technology Accreditation Committee (RTAC)	Co-regulator	• liaise with in relation to compliance and accreditation issues
Australian Health Practitioner Regulation Agency (AHPRA)	Co-regulator	• liaise with in relation to investigations involving clinicians, nurses and/or counsellors who are psychologists
Health Complaints Commission (HCC)	Co-regulator	• liaise with in relation to trends with complaints and the review of ART treatment practices by the Health Complaints Commission
Safer Care Victoria (SCV)	Co-regulator	• liaise with in relation to incidents where patient care is at risk and the potential for collaborative work
Births Deaths and Marriages (BDM)	Regulatory support	• liaise with in relation to the exchange of information

Stakeholder	Type	Actions
Patient Review Panel (PRP)	Regulatory support	• liaise with in relation to any trends with work undertaken or adverse incidents that impact on both entities
Donor Conception Registers Services Advisory Group and the Advisory Panel	Advisory groups	• consultation to inform strategic planning and operational work
Ad hoc advice from subject matter experts.	Advisory group	• consultation to inform operational work

Glossary

Adjuvant therapies	Interventions offered in addition to ART or artificial insemination which are claimed to improve fertility and/or reproductive outcomes
Adverse incidents	An actual or potential contravention of • the ART Act, its guiding principles or its regulations; or • the *Conditions for Registration; or* • conditions of an approval to import/export gametes or embryos. A notifiable incident reported to RTAC as part of accreditation requirements An incident which is or is likely to be harmful to the health or wellbeing of patients, donors or surrogates An incident which is or is likely to be harmful to, affect the viability of or cause the destruction of gametes or embryos Adverse incidents must be reported to the Authority under the *Conditions for Registration*
Advisory panel	The Advisory Panel provides the Authority with current information and advice in relation to ART from scientific, technical, ethical and consumer perspectives
Assisted reproductive treatment (ART)	This includes a medical treatment or procedure which procures or attempts to procure pregnancy in a woman, including in-vitro fertilisation (IVF) and gamete intra-fallopian transfer (GIFT), but excluding artificial insemination
***Assisted Reproductive Treatment Act 2008* (Vic) (the ART Act)**	This Act regulates the use of assisted reproductive treatment and artificial insemination procedures, Victorian surrogacy arrangements, and access to information about donor treatment procedures and resulting births
Central Register	A register held by the Authority with records in relation to donor treatment procedures and the donor, recipient parents and children born as a result of a procedure
Conditions for Registration	The *Conditions for Registration* are imposed, in the public interest, on the registration of ART providers by the Authority
Co-regulator	Any national, other state and territory or Victorian regulator that has complementary objectives or functions, and/or the same regulated entities
Designated officer	A designated officer must be appointed by each registered ART provider who acts as the key point of contact with the Authority in relation to matters relating to the ART Act

Donor	A donor is a person who gives consent to donate their sperm, eggs or embryos including those donors who donated prior to the implementation of legislation
Donor treatment procedure	A donor treatment procedure is a treatment procedure involving sperm, eggs or embryos provided by a donor
Gamete	Sperm or an ovum (egg) from a woman
Guidelines for the import and export of donor sperm, donor eggs or embryos created using donor sperm and/or eggs	These guidelines were established by the Authority to set out what the Authority will consider in deciding whether to approve an application to import or export
Registered ART providers	An ART provider which is registered under the ART Act
Treatment procedure	A procedure which involves ART or artificial insemination
Voluntary Register	A register held by the Authority containing information about individuals involved in Victorian donor treatment procedures, including donors, recipients and children born as a result. The information is voluntarily lodged by individuals in order to match with others to whom they are genetically related