Report on the Ministerial Statement of Expectations for the period 1 July 2016 - 31 December 2017

The Victorian Assisted Reproductive Treatment Authority (VARTA) is required to report on Ministerial Statement of Expectation (SOE) performance standards against VARTA's strategic priorities for 2016 – December 2017. VARTA's actions and achievements in relation to those performance standards are provided below.

Expectation 1: Compliance with the *Assisted Reproductive Treatment Act 2008* (the Act)	
Ministerial performance expectation	Utilising a strategic approach, employ a range of tools and approaches (including regulatory tools), to enable VARTA to satisfy itself that registered assisted reproductive treatment (ART) providers in Victoria have appropriate systems in place to comply with their obligations under the Act. Develop and implement systems and procedures as a regulator, to strategically manage the risk of non-compliance, and identified non-compliance.

VARTA's planned actions and achievements	
VARTA's planned actions	**VARTA's achievements in relation to the action**
The registration system for ART providers under the Act will be reviewed/revised by 30 June 2017 by: (a) adopting and implementing protocols where appropriate to: • identify and assess any relevant risk and matters in the public interest. This includes regularly engaging with the ART providers to identify any issues in performance of their regulatory responsibilities and programs, activities and procedures under the Act and any inconsistencies in their understanding of this regulatory framework • implement a risk and evidence-based approach to responding to identified relevant risk and matters in the public interest, including the imposition of conditions for registration targeted to address this	• Reviewed the ART clinic registration system including the *Conditions for Registration*, areas of key risk and following consultation, imposed new conditions to target identified areas of weakness including: ○ ART providers must have appropriate governance, processes and systems in place to ensure compliance with the Act, the *Conditions for Registration* and all other applicable laws, regulations and conditions, and must provide evidence of the same when requested. ○ A number of attestations must be provided by designated officers at the end of each financial year. ○ ART providers must provide the Authority with a copy of all Reproductive Technology Accreditation Committee (RTAC) accreditation, audit and surveillance reports under the RTAC Code of Practice. ○ Advertising, claims and comparisons must not be misleading or deceptive, must be verifiable, and must comply with the Health Practitioner Regulation National Law and Guidelines for Advertising Regulated Health Services.

• require ART providers to have systems in place to ensure compliance with the Act. (b) review opportunities to streamline requirements for ART providers (e.g. development of on line forms).	• Annual compliance review and engagement process implemented at end June 2017, with a series of meetings with all registered ART providers to discuss compliance with the above. • Developed an adverse incident reporting form to facilitate consistent, higher quality reporting from registered ART providers. • Corresponded and liaised with RTAC in relation to breaches of the legislation at Melbourne IVF and Monash IVF to enable a focus on areas related to the breaches during the annual audit against the RTAC *Code of Practice* for accreditation. • Taking a systemic approach, provided feedback for the review of the RTAC *Code of Practice* for the accreditation scheme. The revised *Code of Practice*, October 2017, now includes: annual auditing of cryostorage of gametes and embryos; public information requirements; regulatory compliance and inclusion of a potential or actual breach of legislation as a serious notifiable event. The revised RTAC *Code of Practice* also establishes that "an ART unit includes…independent practitioners and individuals accountable for the delivery of services to the patient". This incorporates clinicians and their practices into the RTAC accreditation audits. As a result, VARTA will be better placed to monitor clinical governance and other matters on receipt of an RTAC audit report. • Liaised with Australian Health Practitioner Regulation Authority (AHPRA), RTAC, and the Victorian Health Complaints Commissioner in relation to a notification by a clinician at Primary IVF about other personnel (reported to be under investigation by AHPRA). Reviewed the report of a special audit of complaints policies and processes at Primary IVF by an independent external auditor and the regular audit by RTAC in November 2017. Ongoing liaison with the Designated Officer and the RTAC Chairperson to monitor risk management. Communicated with a Ministerial Adviser in relation to risk of media coverage. • Monitored trends in the reporting of adverse incidents by registered ART providers and RTAC accreditation reports, to enable any areas of potential concern to be followed up and addressed.
VARTA will implement a risk and evidence-based approach to responding to contraventions of the Act, regulations or registration under the Act by 30 June 2017, which: • takes into account VARTA's ability to impose conditions of registration on registered ART providers	• Developed a Regulator Plan for publication on the VARTA website in January 2018, taking a risk and evidence-based approach to VARTA's regulatory work. • Established processes and procedures related to the receipt of adverse incidents reported including potential contraventions of the Act and an escalation of these reports to investigation where appropriate. • Monitoring and analysis of adverse incident reports and RTAC accreditation audit reports to facilitate an evidence-based approach, with areas of risk identified and followed up.

• takes into account VARTA's powers under Part 11 of the Act • identifies means to share information with and provide education to ART providers about their regulatory responsibilities under the Act to promote a shared understanding in the public interest.	• Imposed specific *Conditions for Registration* on Melbourne IVF and Monash IVF in response to breaches of the Act following investigative work with the cooperation of these providers, informing the Health Minister and Department of Health and Human Services (DHHS) of findings and conditions imposed. • Investigated potential/actual contraventions by Melbourne IVF in relation to statutory storage periods and embryo disposal while an application for the extension of storage to the Patient Review Panel was pending, communicating information regarding their responsibilities and compliance standards. Reviewed changes to systems implemented, reports of modifications made to the Melbourne IVF patient information system and audits conducted to the end of 2017, as required under the revised *Conditions for Registration*. • Investigated a contravention of the Act by Monash IVF in relation to the transfer of two embryos formed using sperm donated by two different donors, reviewed monthly reports required to detail progress made with systemic changes implemented to the end of the 2017-18 financial year, including changes to the patient information system by the end of December 2017. Consulted AHPRA in relation to the treating clinician's treatment plan to transfer two embryos. • During the investigation of the above Monash IVF contravention of the Act, advised Monash IVF that VARTA's powers under Part 11 of the Act would be utilised unless unredacted information was provided. • Provided information to registered ART provider staff on request and education sessions at staff meetings in relation to legislative compliance.
VARTA's stakeholder management plan and risk management plan will (in a proportionate way) be reviewed and updated.	• Reviewed and updated VARTA's stakeholder management and risk management plans.

VARTA will continue to advise the Minister in a timely and informed manner of breaches of the Act and conditions for registration and matters and developments of importance or concern, including any relevant recommendations.	• Minister informed of the following potential/actual contraventions of the Act:
	  ○ Melbourne IVF storage incidents and embryo disposal
	  ○ Melbourne IVF import of six instead of the five donated embryos approved for import by VARTA
	  ○ Monash IVF incident involving the transfer of two embryos produced using sperm from two different donors.
	• VARTA provided the Minister with an initial notification of the incident, and then full reports of VARTA's investigation as above.

Expectation 2: Fertility education	
Ministerial performance expectation	Identify and implement targeted measures to provide education about fertility.

VARTA's planned actions and achievements	
VARTA's planned actions	**VARTA's achievements in relation to the action**
Review the Department's material on the Better Health Channel relating to fertility by 31 March 2017	• Reviewed Departmental material on the Better Health Channel relating to fertility by 31 March 2017 and provided proposed amendments to content.
Recommend means to support information on the Better Health Channel and through other avenues of public education relating to fertility by 31 March 2017	• Recommended information to address information gaps to the Better Health Channel by 31 March 2017 and that VARTA provide information to the Better Health Channel in an ongoing way.
Implement any agreed improvements in accordance with agreed time frames	• *Fertility Week* information was disseminated by the Better Health Channel in October 2017. • Further information on fertility has been drafted for the Better Health Channel for finalisation in January 2018.
Publish a fertility web tool on the *Your Fertility* website by 1 September 2016	• Published a fertility web tool (*Fertility Potential Indicator*) on the *Your Fertility* website by 1 September 2016 resulting in over 85,000 page views to 9 November 2017. In the 2016-17 financial year there were around 2.75 million *Your Fertility* website users compared with around 3 million website users the previous financial year. Further work is underway in partnership with The Robinson Research Institute to further enhance the *Fertility Potential Indicator* with funding from the Commonwealth Government.
Conduct and evaluate *Fertility Week* 2016 (first week of September 2016) with a focus on the modifiable factors that can potentially improve success with ART, aiming for a 10 per cent increase in website visitors by June 2017.	• Conducted and evaluated *Fertility Week* 2016 (first week in September 2016) with a focus on modifiable factors that can potentially improve success with ART. *Fertility Week* 2017 was conducted from 15 - 21 October 2017 with a focus on chemicals in the home and fertility. With extensive social and traditional media coverage, a reach of over 72 million was achieved based on circulation data. Over 206,000 visits to the Your Fertility website were received during *Fertility Week* 2017 and the following week.

Additional achievements in relation to *Your Fertility*	• Developed a plan and obtained funding of $956,000 from the Commonwealth Government to expand the *Your Fertility* program from 1 April 2017 to 30 June 2019 in partnership with Andrology Australia, the Jean Hailes Research Unit and The Robinson Research Institute. See VARTA 's Annual Report 2017, pages 16-17. • Participated in the Implementation Reference Group for the *Women's sexual and reproductive health plan* released by the Minister for Health, with attendance of VARTA staff at planning workshops to date.

Expectation 3: Implementation of the *Assisted Reproductive Treatment Amendment Act 2016* (ART amendments)	
Ministerial performance expectation	Work with stakeholders, including the Department, Registry of Births Deaths and Marriages (BDM) and registered ART providers to ensure that VARTA can carry out its new obligations under the ART amendments effectively and by the commencement date. Ensure that the experience of donors, donor-conceived people and other donor-conception stakeholders is positive, and carry out new functions sensitively to meet the expectations of stakeholders.

VARTA's planned actions and achievements	
VARTA's planned actions	**VARTA's achievements in relation to the action**
Establish processes and procedures to support VARTA's new functions	• Consulted with registered ART providers at quarterly inter-clinic meetings and with individual staff to streamline processes in relation to the submission of birth notifications from donor treatment for the Central Register. • Established processes and procedures to support VARTA's new functions under the *Right to Know* legislative ART amendments to facilitate legislative compliance, including reminders relating to legislative timelines in the software used to manage the donor registers and case management. • Developed and documented information and records management procedures as well as counselling processes to meet legislative obligations under the Act.
Publish educational material and application forms on VARTA's website to support the new amendments	• Revised the VARTA website structure and information for the general public and stakeholders including application forms for the donor registers, information sheets and brochures. • Held presentations to staff at all registered ART providers that offer donor treatment about the changes in legislation and ART provider responsibilities to enable the support of patients/donors.
Arrange transfer of the Central Register and Voluntary Register (the donor registers) from BDM to VARTA	• Met and consulted regularly with DHHS and BDM prior to and following implementation of the ART amendments, with smooth transition in relation to the transfer of responsibilities. A Memorandum of Understanding (MOU) was established between VARTA and BDM to enable information exchange as required by the ART amendments.
Train relevant staff to undertake the new and expanded functions	• Established infrastructure and recruited and trained staff to support the ART amendments and processed applications to the donor registers from 1 March 2017 and provided counselling. See VARTA's Annual Report 2017, pages 8-13.
Conduct meetings with key stakeholders via the Donor Registers Reference Group and other meetings to gather feedback on service delivery planning	• Consulted with the Donor Registers Reference Group (comprised of donor-conception stakeholders) quarterly in relation to processes, form letters and public education materials.

Implement an evaluation plan for the donor registers service to identify opportunities for ongoing improvements	• Implemented an evaluation framework to gather feedback on management of the donor registers and associated service provision to enable continual review and improvement. Surveys indicated that 98% of service recipients were 'satisfied 'or 'very satisfied' with VARTA donor conception register services. Qualitative evaluation report of interviews with a sample of service recipients, utilising an external consultant, has provided positive feedback about VARTA services (reports provided to DHHS).

Expectation 4: Improving accountability and transparency	
Ministerial performance expectation	Demonstrate accountability and transparency in administration and enforcement of the Act by measuring VARTA's performance against its functions under the Act and its strategic objectives, and reviewing regulatory practices annually. Publish this assessment in VARTA's annual report. Seek and assess feedback annually from key stakeholders, including DHHS, ART providers, BDM and donor conception stakeholders, and adopt appropriate continuous improvement measures to address feedback.

VARTA's planned actions and achievements	
VARTA's planned actions	**VARTA's achievements in relation to the action**
Maintain good, effective organisational strategic planning processes	• Effective organisational strategic planning processes maintained. • The VARTA Annual Report 2017 provides performance outcomes against strategic objectives and functions under the Act in the report of operations. • The Stakeholder Management Plan was reviewed, updated and implemented with feedback sought regularly to inform continuous improvement measures. • Board and staff workshop was held in October 2017 and a Regulatory Plan developed with the involvement of KPMG for publication on the VARTA website early 2018. • A strategic planning workshop was held with board and staff in December 2017. • The Stakeholder Management Plan was reviewed and regulatory aspects were incorporated within the Regulator Plan. Regular consultation with DHHS, ART providers. • Published all *Conditions for Registration* on the VARTA website.
Seek feedback from registered ART providers biannually	• Feedback has been sought from registered ART providers about issues at quarterly inter-clinic meetings. • Met with individual designated officers of all registered ART providers in mid-2017, seeking feedback on the *Conditions for Registration* and addressing any concerns about compliance with the Act.

Provide information about the Victorian ART sector and report against key performance and regulatory indicators in its 2017 annual report, including in respect of its new statutory functions and matters agreed with the Department of Health	• See Operational Report within VARTA's Annual Report 2017, pages 4-21. Aspects of performance related to the SOE are embedded within this annual report. See VARTA's Annual Report 2017, page 7.
Review and assess the relevance of data and information collected from ART providers and make recommendations to the Department where appropriate by 30 June 2017	• Consulted registered ART providers and revised the ART data tables for the 2016 and 2017 VARTA annual reports, communicating with DHHS as part of this process. Changes were necessary to capture outcomes associated with changing practices, and to provide outcomes for different age groups of women treated.