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| Consultation summary - reforms to health regulation in Victoria |
| Summary of themes and outcomes |
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Contents

[Context 1](#_Toc173497614)

[Proposed reforms in the consultation paper 2](#_Toc173497615)

[Participation in consultation 3](#_Toc173497616)

[Summary of submissions 3](#_Toc173497617)

[Part one: summary of themes and outcomes 4](#_Toc173497618)

[Submissions 4](#_Toc173497619)

[Key submission themes 4](#_Toc173497620)

[Response to key submission themes 5](#_Toc173497621)

[Part two: summary of themes and outcomes 6](#_Toc173497622)

[Submissions 6](#_Toc173497623)

[Key submission themes and responses 6](#_Toc173497624)

[Next steps 12](#_Toc173497625)

# Context

In December 2023, the Minister for Health announced the establishment of the Department of Health’s (the department) Health Regulator and that the Victorian Government is developing reforms to modernise the regulation of assisted reproductive treatment (ART) by transferring responsibility for the regulation of ART from the Victorian Assisted Reproductive Treatment Authority (VARTA) to the department.

On 29 April 2024, the department released the consultation paper *Reforms to health regulation in Victoria* to seek stakeholder views, build an understanding of the reforms, and support their implementation. The consultation paper is available on the department’s website at [Reforms to health regulation in Victoria](https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria) <https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria>. A summary of the proposals in the paper is provided below. Consultation was open for five weeks (until 31 May 2024).

As stated in the consultation paper, individual submissions will not be made public by the department, however this anonymised summary of submissions is being published. The majority of submissions were either unclear about whether the submission was private and confidential or were marked as private and confidential, and a large number contained identifying information, personal information, or health information.

## Proposed reforms in the consultation paper

The consultation paper was divided into two parts:

**Part one** ­– consulted on proposed reforms to improve the compliance and enforcement tools available under health portfolio legislation.

**Part two** – consulted on proposed reforms to the regulation of ART under the *Assisted Reproductive Treatment Act 2008*.

### Part one: improved compliance and enforcement tools

Part one included proposed reforms to improve the compliance and enforcement tools available to regulate:

* Cooling tower and water delivery systems under the *Public Health and Wellbeing Act 2008*.
* Drinking water under the *Safe Drinking Water Act 2003*.
* First aid services under the *Non-Emergency Patient Transport and First Aid Services Act 2003*.
* Medicines and poisons under the *Drugs, Poisons and Controlled Substances Act 1981*.
* Non-emergency patient transport under the *Non-Emergency Patient Transport and First Aid Services Act 2003*.
* Pest control operators under the *Public Health and Wellbeing Act 2008*.
* Private hospitals, day procedure centres and mobile services (or health service establishments) under the *Health Services Act 1988*.
* Radiation sources under the *Radiation Act 2005*.

Part two of the consultation paper also noted the proposal to improve compliance and enforcement tools in the Assisted Reproductive Treatment Act and sought specific feedback in relation to that Act.

The proposed reforms aim to establish for the Health Regulator a consistent baseline of appropriate regulatory tools to enable graduated, risk-based and proportionate regulation. The proposed tools include powers to issue infringement notices, issue improvement and prohibition notices, accept enforceable undertakings, and to require the provision of information or documents to support compliance monitoring. Currently some of the above regulatory schemes have some, equivalent, or none of those regulatory tools. Therefore, new powers are only proposed for some Acts where the power (or equivalent power) is not currently available.

### Part two: reforms to the regulation of ART

Part two included proposed reforms to the regulation of ART including:

* Transferring the regulatory functions of registering ART providers and monitoring and enforcing compliance to the department’s Secretary.
* Transferring responsibility for maintaining and managing the Central Register and Voluntary Register (the registers) to a new Donor Conception Registrar within the department, and administratively separate from the Health Regulator.
* Replacing the requirement for the regulator’s preapproval to bring donor gametes or embryos formed from them into, or out of, Victoria with a certification requirement.
* Removing the mandatory counselling requirements before disclosure of information from the registers or lodgement of a contact preference. This is proposed to be replaced with a requirement that the Donor Conception Registrar provide prescribed explanatory material to the person which will cover matters currently required to be covered during mandated counselling as well as consideration of funding for an appropriate organisation to deliver counselling for those who wish to access it.
* Removing the functions relating to education, consultation and research promotion from the ART Act.
* Improving regulatory tools in line with reforms being proposed to other health regulatory schemes.

# Participation in consultation

The consultation paper was published on the department’s website. A feedback template was also provided which could be used to submit a response. The webpage had nearly 2,500 page views during consultation (up until 2 June 2024). The consultation opportunity was promoted on the department’s website homepage and progressively published on individual regulatory scheme webpages on the department’s website.

The department also directly contacted over 21,000 stakeholders by email to notify them of the consultation opportunity. This included some community and consumer groups, professional associations and peak bodies, government and public entities, duty holders, insurers, researchers or academics, and interested individuals. A summary and breakdown of stakeholders directly notified of the consultation opportunity is provided in **Table 1**.

Table 1: summary of stakeholders directly notified of the consultation opportunity

| Stakeholder group | Number\* |
| --- | --- |
| Community and consumer groups | ~18 |
| Professional associations and peaks | ~101 |
| Government and public entities (Victorian and other jurisdictions) \*\* | ~35 |
| ART providers | 13 |
| Non-emergency patient transport providers | 10 |
| First aid service providers | 46 |
| Water authorities and related peak bodies | 20 |
| Health service establishments | 171 |
| Radiation Act duty holders | ~20,713 |
| Other (such as insurers, academics, and interested individuals) | ~23 |
| **Total** | ~21,150 |

\*Some numbers are approximate to account for undeliverable emails and targeted emails by individual department staff with existing relationships with interested stakeholders.

\*\*For example, co-regulators, tribunals, commissioners. This does not include Victorian departments.

## Summary of submissions

The department received 148 submissions. Of these submissions, 29 responded to part one only (improved compliance and enforcement tools), 102 responded to part two only (reforms to the regulation of ART), and 17 responded to both parts of the consultation paper.

A summary of themes and a more detailed breakdown of submissions received on each part of the consultation paper is provided in the sections Part one: summary of themes and outcomes and Part two: summary of themes and outcomes.

The department thanks everyone who provided feedback through this consultation process and acknowledges the time and effort taken to contribute. The feedback has informed the design of these proposed reforms. In addition, the department is grateful for the feedback provided on other matters outside of the scope of this consultation. This feedback will inform planning for any further legislative or regulatory reforms.

# Part one: summary of themes and outcomes

## Submissions

In total, 46 submissions responded directly to part one of the consultation paper about the proposal to improve the Health Regulator’s compliance and enforcement powers (noting that 17 submissions responded to both parts of the consultation paper). Most of the submissions (74 per cent; or 34 submissions) received on this part of the consultation paper were from regulated entities[[1]](#footnote-2) or professional associations and peak bodies representing regulated entities. A breakdown of the stakeholder groups that provided submissions directly on part one is in **Table 2.**

Table 2: summary of submissions about reforms to improve compliance and enforcement powers

| Stakeholder group | Part 1 only | Both parts | Total |
| --- | --- | --- | --- |
| Community and consumer groups | 0 | 2 | 2 |
| Professional associations and peaks | 12 | 4 | 16 |
| Government and public entities\* | 1 | 1 | 2 |
| Regulated entities (including ART providers, non-emergency patient transport services, first aid services, water agencies, health service establishments, radiation use licensees) | 15 | 3 | 18 |
| Other (such as insurers, academics, and interested individuals, unknown) | 1 | 7 | 8 |
| Total | **29** | **17** | **46** |

\*For example, co-regulators, tribunals, commissioners. This does not include Victorian departments.

## Key submission themes

Most submissions clearly supported, in principle, improving the compliance and enforcement powers of the Health Regulator to allow risk-based, graduated and proportionate regulation.

Feedback also raised issues relevant to implementation, highlighting that implementation will be essential to achieving the reform objectives. This included, in summary, submissions noting the need for:

* A Health Regulator compliance and enforcement policy or similar published resource to support the appropriate use of the new and existing compliance and enforcement powers. This includes published information about the powers.
* Adequate resourcing for the Health Regulator to effectively monitor and enforce compliance (i.e. use the new compliance and enforcement powers). This includes the need for regulatory staff with the appropriate expertise, skills, and training to support appropriate and consistent decision making.
* The Health Regulator to actively educate and communicate with the public and regulated entities to support transparency, understanding and compliance.
* A delayed commencement of the new compliance and enforcement powers to allow time for the above and for regulated entities and the Health Regulator to prepare.

Submissions that clearly did not support the proposed reforms or did not support them in full raised, in summary: sector specific issues; concerns about regulatory burden; the need for appropriate safeguards; or the adequacy of the department’s current guidance, support, or implementation of existing regulatory requirements or compliance and enforcement tools. For example:

* A submission argued that operational and system improvements to SafeScript should be completed before new compliance and enforcement powers are introduced.
* Some submissions raised concerns that the department may not have the relevant sector (ART) expertise required to regulate the ART sector.
* Some submissions argued that a case has not been made for why the Safe Drinking Water Act should be amended to introduce a new power to issue infringement notices for prescribed offences (the only proposed reform to this Act), in light of the powers already included in that Act, which include powers to compel provision of information and accept enforceable undertakings.

A small number of submissions did not make clear whether they did or did not support the proposals.

## Response to key submission themes

The feedback from consultation has been and will continue to be used by the department to inform the design of the proposed reforms and (subject to their introduction and passage in Parliament) plan for their implementation. In response to operational and implementation issues raised in submissions, the department confirms that, if the proposed legislative amendments are made, the Health Regulator would:

* Before commencement of the improved compliance and enforcement powers:
* Develop and publish an updated compliance and enforcement policy.
* Update existing public guidance about using SafeScript and associated regulatory requirements.
* Continue to maintain internal policies, procedures, and training to support the appropriate, effective, and consistent implementation of compliance and enforcement powers.
* Continue to develop and refine engagement and communications strategies to provide compliance guidance and support to regulated entities and improve understanding of regulatory requirements and the Health Regulator’s role and powers.
* Publicly report on implementation of the improved compliance and enforcement powers in the Department of Health’s 2024-25 and 2025-26 annual reports, and report on the Health Regulator’s activities in all future department annual reports.
* As is usual process, develop and make any prescribed infringement offences in regulations in accordance with the *Subordinate Legislation Act 1994* and *Attorney-General’s Guidelines to the Infringements Act 2006*, including meeting consultation requirements and assessing the suitability of an offence being an infringement offence.

# Part two: summary of themes and outcomes

## Submissions

In total, 119 submissions responded directly to part two of the consultation paper about proposed reforms to the regulation of ART (17 of those responded to both parts of the consultation paper). Most of the submissions (over 60 per cent) received on this part were from individuals with lived experience of donor conception. Parents who have undergone donor conception treatment represented the largest number of responses. The department is grateful to those who shared their lived experience and to all stakeholders who took the time to contribute to the consultation.

A breakdown of the stakeholder groups that provided submissions on part two is in **Table 3**.

Table 3: summary of submissions received about part two

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| --- | --- | --- | --- | --- |
| **Stakeholder group** | **Part 2 only** | Both parts | **Total** | |
| Solo mothers by choice\* | 47 |  | 47 | Individuals with lived experience  **75** |
| Parents of donor-conceived people / recipients of donor gametes | 16 |  | 16 |
| Donors | 2 |  | 2 |
| Donor conceived people | 6 | 4 | 10 |
| ART providers | 3 | 2 | 5 |  |
| Academics/researchers | 7 |  | 7 |
| Community and consumer groups / professional associations and peaks / Government and public entities\*\* | 9 | 7 | 16 |
| Other (former counsellors / health consumers / other interested individuals) | 12 | 4 | 16 |
| **TOTAL** | 102 | 17 | 119 |

\* Only used where the person submitting has identified as such

\*\*For example, statutory bodies. This does not include Victorian departments.

## Key submission themes and responses

### Regulatory functions and tools

**Proposed transfer of regulatory functions to the Department - feedback received**

Feedback on the proposed transfer of ART regulation to the Health Regulator emphasised that ART is a highly specialised, complex and rapidly changing field. For this reason, some respondents preferred an independent specialist regulator outside the department – raising concerns about the efficacy of a consolidated regulator in monitoring and addressing the specific risks and issues relevant to ART. Submissions from a variety of stakeholder groups emphasised that the Health Regulator will need to have the requisite knowledge, expertise and dedicated resourcing to be an effective regulator in this space. Some with lived experience also recommended that the department establish a Donor Conception Advisory Group to advise the department on the views of those affected by donor conception including representatives with lived experience: donor conceived people, donors, parents of donor conceived people and LGBTIQA+ individuals.

Other submissions supported the transfer of regulation to the department on the basis that it would lead to more efficient, streamlined, and effective regulation of the sector. The administrative separation of regulatory and register functions was also favoured by some responding to the consultation. ART providers communicated the importance of having adequate time and clarity in relation to any changes as a result of the transfer that will impact them.

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| **Response to feedback**  The department acknowledges the complexity of ART and the need for specialist regulation in this area. It is important to note that bringing ART regulation into the Health Regulator would not mean that ART would no longer be subject to specific regulation under the ART Act. The ART Act and associated regulations would continue to apply to ART, as they do now, but monitoring and enforcement under the Act would be undertaken by the Health Regulator. Since the introduction of the ART Act, we have seen significant scientific and societal changes related to assisted reproductive treatment. It is critical we have a modern, fit-for-purpose regulator with the expertise and tools they need to protect and support Victorians involved in or affected by ART.  The Health Regulator is well placed to regulate the sector and ensure assisted reproductive treatment is as safe and accessible as possible. Consolidation of regulatory functions under the Health Regulator allows us to respond more rapidly and allocate appropriate resources to key priority areas as issues arise.  Staff working in the Health Regulator will have the appropriate skills and expertise to effectively carry out the regulatory functions under the Act, reflecting the need for specialist regulation.  In line with stakeholder feedback, the department will establish a donor conception advisory group to assist the department with the implementation of the reforms and provide ongoing advice and expertise in relation to donor conception. |

**Improved compliance and enforcement powers - feedback received**

Feedback on the proposed new compliance and enforcement powers for the Health Regulator under the ART Act stressed that the application of penalties should be proportionate and take into account that ART providers can vary from small practices to extremely large multi-national businesses. Some feedback was received that the regulator must be able to inspect and audit providers.

Providers and practitioners requested clarification of the interaction between the regulation of doctors by the Health Regulator and the Australian Health Practitioner Regulation Agency (Ahpra).

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| **Response to feedback**  The Independent Review of Assisted Reproductive Treatment by Michael Gorton AM (known as the Gorton Review) recommended that the Act should be amended to provide the regulator with a more extensive and graduated set of powers to proportionately respond to risk and support improved compliance.  Proposed new mid-range compliance and enforcement tools would not be the only enforcement actions available to the Health Regulator following the proposed reforms. Serious actions will be able to be taken in response to serious breaches. The existing powers to impose conditions on a provider’s registration and to fully or partially suspend a registration would remain in the Act, as will the power under the Act to enter premises and inspect documents. The new power to issue a notice to provide information or produce documents is intended to allow the Health Regulator to monitor compliance via audits. The new powers to issue an improvement notice and prohibition notice, and the power to accept an enforceable undertaking, are intended to allow the Health Regulator to target enforcement appropriately and enhance the regulator’s ability to address non-compliance proactively, as well as reactively. |

**Changes to requirements for moving donated gametes and embryos created from them, into or out of Victoria - feedback received**

Feedback was received from donor conceived people that there should be no loosening of requirements for moving donor gametes or embryos formed from them in to or out of Victoria. Concerns were also raised that breaches or errors may not be discovered until after the movement of the gametes or embryos has occurred and they have been used in a treatment procedure.

ART providers requested clarification on how the proposed certification process will operate but overall supported the change as a way to improve transparency and reduce unnecessary regulatory burden and delays for patients.

In relation to the proposed criteria that must be certified prior to moving donor gametes or embryos formed from them in to or out of Victoria, feedback was received to the effect that some of the criteria should be more stringent. In particular, some stakeholders viewed the requirement to make ‘best efforts’ in relation to maintaining family limits as insufficiently rigorous.

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| **Response to feedback**  There is no intention to weaken requirements for the movement of donor gametes or embryos formed from them. The proposed change - recommended by the Gorton Review - relates to the process and mechanism for oversight and aims to reduce unnecessary barriers associated with bringing donor gametes or embryos formed from them into or taking them out of Victoria. Requirements relating to the use of donated gametes or embryos formed from them in treatment will remain the same, including those relating to counselling, consent and provision of information for the registers.  As envisaged by the relevant recommendation in the report from the Gorton Review, these reforms seek to balance reasonable access to donated gametes or embryos formed from them, for those seeking to start or grow their families, with effective safeguards in relation to consent and accurate record keeping, to allow donors to be identified and contacted. This change does not represent a shift to self-regulation. The Health Regulator will monitor and enforce compliance. A person making a certification will also be required to keep relevant records and it will be an offence to make a false or misleading certification.  Should the reforms be introduced, the department will work to ensure that the requirements of the certification process are clearly communicated to ART providers in a timely manner. |

### Registry functions, counselling and education

**Transfer of registry functions to a Donor Conception registrar - feedback received**

Feedback on the proposed transfer of the donor conception registers to a new Donor Conception Registrar within the department highlighted the value of the current support VARTA provides.

In particular, submissions received from parents of donor conceived people noted that they highly value VARTA’s support in helping them navigate the complexities associated with donor conception, including in relation to potential risks for themselves and their children. Overall, they were opposed to VARTA being wound up.

Stakeholder feedback also emphasised the sensitive nature of information on the registers and the importance of information being released to applicants in a supportive, trauma-informed way. Should the registers be transferred into the department, many stakeholders emphasised that staff dealing with disclosure from the registers must be appropriately qualified and experienced, with specialist knowledge in donor conception and matters relating to LGBTIQA+ families.

Some stakeholders indicated that they would prefer the registers to sit with Births, Deaths and Marriages (BDM) as BDM has experience managing the collection and disclosure of genetic information, and its functions align with management of the donor conception registers.

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| **Response to feedback**  The department acknowledges that while donor conception is an increasingly common method of family formation, it can present unique challenges and complexities for the individuals involved. The department also acknowledges the high regard many stakeholders have for the support they have received from VARTA.  It is proposed the donor conception registers would be housed in a different area of the department from the Health Regulator to ensure appropriate separation of functions. The department is committed to ensuring that staff who work with the registers have the appropriate skills and expertise, as well as an understanding of the complexities associated with donor conception, so that they are able to support Victorians effectively and sensitively. In addition – as mentioned above - the department will establish a donor conception advisory group to assist with the implementation of the reforms and provide ongoing advice and expertise in relation to donor conception.  There is no proposal to change the scope of information in the registers or the rights of access to the registers. The key steps in the process will remain the same, aside from the removal of mandatory counselling and donor-linking from the legislation.  The department acknowledges how important the information held on the registers is for donor conceived Victorians. A formal Registrar will ensure this information is secure, well managed and accessible for those who can apply. |

**Removal of mandatory counselling requirements relating to access to the registries - feedback received**

Many stakeholders provided feedback that people affected by donor conception may continue to face significant challenges associated with the disclosure of information. This might include donor conceived people who find out they are donor conceived later in life, or donors who donated under previous conditions of anonymity. While there were some who favoured counselling remaining mandatory on the basis that it may lead people to consider issues they had not thought of, there was generally support for people being able to choose whether or not they undertake counselling. Even if not mandated, many stakeholders responded that counselling should continue to be available to those who wish to have it, and the overall preference was for VARTA – as an organisation with specialist donor conception experience ­– to continue to deliver counselling and for that delivery to remain integrated with the release of information from the registers.

Feedback noted that if funding is provided to an external body to provide counselling, there is a need to ensure that people are referred/connected to those services in a supportive, trauma-informed way. Many stakeholders emphasised that any funded external service(s) must have appropriately skilled and qualified counsellors, with experience in donor conception.

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| **Response to feedback**  Under the reforms, counselling would remain a fundamental and important safeguard of the Act. The proposed reforms relate solely to counselling before information on the registers can be accessed or a contact preference lodged. Transitioning from mandatory to voluntary counselling respects the right of individuals to make an informed choice about their counselling needs.  The department will establish arrangements for funding an appropriate organisation, with suitably qualified and experienced counsellors, to deliver quality, culturally safe counselling for those involved in accessing the registers who wish to access counselling.  All other counselling requirements in the Act would continue, meaning donors and recipients would still be required to undertake counselling before they consent to the use of donated material in a treatment procedure. This counselling must cover certain matters including, where relevant, advising any children who may be born from a treatment procedure about their donor origins and rights to information. Current requirements for a counsellor to confirm the maturity of a child involved in accessing information on the registers are also proposed to be retained.  In addition, the new Donor Conception Registrar would be required to provide explanatory material to anyone who applies for information from the registers or who can lodge a contact preference under the Act. This material would be developed with specialist input from experts and deal with matters currently covered during mandatory counselling, such as the rights and duties of the parties involved, the potential implications of disclosure, and where to access support.  The department asked for feedback on the proposed matters to be included in that information or ‘explanatory material’. Feedback reflected concerns that provision of information is not an adequate replacement for counselling. Some stakeholders took this to mean that the person would be given a general ‘information sheet’ The ‘explanatory material’ provided by the Donor Conception Registrar would be developed with specialist input (including from the donor conception advisory group to be established) and is envisaged to be more sophisticated and relevant to the issues that may arise for the individual than a single general ‘information sheet’. The department will also consider including information in the explanatory material about possible safety issues that may arise in the context of disclosure from the registers. The matters required to be covered by the explanatory material would be prescribed in the regulations. |

**Donor linking functions - feedback received**

Donor linking was referenced in some of the feedback that noted the value of VARTA’s current management of the registers.

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| **Response to feedback**  Under the ART Act, ‘donor-linking’ does not refer to the process of ‘matching’ individuals who are connected genetically, which occurs through the registers. The ‘donor linking’ provisions allow VARTA to facilitate the exchange of information or correspondence between people affected by donor conception or assist them to arrange contact. Those provisions do not allow disclosure of identifying information without consent, nor do they allow disclosure of information from the registers. Authority to disclose information from the registers is dealt with in other provisions of the Act.  Under the proposed reforms, the requirements and authorisations for ‘matching’ individuals and disclosing information from the registers will be retained. The ‘donor linking’ provisions would be removed from the Act, recognising that individuals may wish to manage these matters in a range of ways and feel comfortable doing so. However, the Donor Conception Registrar and skilled staff will continue to be able to support exchange of information with the consent of both parties, if that is appropriate. |

**Research, education and consultation functions – feedback received**

Concerns were also raised that the public education function currently undertaken by VARTA would not remain in the Act. Many stakeholders emphasised that VARTA’s educational resources are relied on by the public both in Victoria and in other jurisdictions. Responses communicated that there is a need to ensure that Victorians continue to have access to up-to-date, independent, evidence-based educational resources and information about infertility, ART and donor conception.

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| **Response to feedback**  The department acknowledges that the public education resources developed by VARTA are highly valued by the community. These resources cover prevention of infertility and navigating fertility treatment, as well as donor conception materials. The department is working to confirm fit-for-purpose arrangements to ensure continued access to this information for the public, including its ongoing maintenance.  The department is also aware of the desire for continued access to ART data currently collected by VARTA and published in its Annual Report. If the reforms are introduced, ART providers would continue to be required to report data in accordance with the conditions of registration. The department will look at appropriate ways this data might be made available. |

**Transition and implementation - feedback received**

In relation to the proposed transition of functions, stakeholders noted the:

* importance of data security and protection of important historical records held by VARTA during and after the transfer of the registers,
* need for clear communication and engagement with stakeholders about changes that may impact them, and
* provision of adequate time for registered ART providers to make any necessary adjustments to ensure compliance.

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| **Response to feedback**  The department fully appreciates the need to protect the sensitive and important personal information held on the registers. Data security and retention obligations are being very carefully considered and will be an integral part of transition planning. The department and VARTA will work closely with stakeholders to ensure a smooth transition and facilitate continuity of service. |

**General feedback and future reforms – feedback received**

Other general matters raised in relation to the proposed reforms included that:

* the reforms should specifically refer to the Guiding Principles in the Act
* wherever possible, the Act should aim to take a more inclusive, modern view of families and language should be updated to reflect this.

Stakeholders also made many constructive and considered proposals in relation to possible future reforms to the ART Act.

The department is grateful for the many proposals for possible future reforms to the ART Act. These will be compiled and inform planning for further legislative and regulatory reforms.

# Next steps

Feedback from consultation was used by the department to inform the design of the proposed reforms and is being used to plan for their implementation (subject to the reforms being passed in Parliament). The department will continue to have further targeted discussions with some stakeholders in relation to feedback received.

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1. The Department of Health regulates thousands of professionals, organisations and businesses across the state with the objective of preventing serious harm to the health and wellbeing of Victorians. The consultation paper and this summary use the term *regulated entities* to refer collectively to any person or other entity regulated by the department under the Acts proposed for amendment. [↑](#footnote-ref-2)