

# National Eye and Tissue Sector Framework

August 2022



# Contents

- Preamble ..... 1
- Acknowledgements ..... 1
- Strategic Context ..... 3
  - PricewaterhouseCoopers Report: Analysis of the Australian Tissue Sector ..... 4
- The National Eye and Tissue Sector Framework ..... 5
  - Vision ..... 5
  - Objectives ..... 5
  - Guiding Principles ..... 5
  - Stakeholders ..... 6
- The National Framework ..... 6
  - 1. Scope ..... 7
  - 2. Purpose ..... 8
  - 3. Governance and oversight ..... 8
  - 4. Self-sufficiency, importation and exportation of tissues and tissue-based products ..... 9
  - 5. Tissue supply costs ..... 10
  - 6. Stakeholder engagement ..... 11
  - 7. Research ..... 11
  - 8. Data and reporting ..... 12
- Progressing the Framework ..... 12
  - Ongoing Review ..... 12
- Appendices ..... 14
- Appendix A – The Australian Eye and Tissue Sector ..... 14
  - Legislative Framework ..... 14
  - Eye donation and transplantation ..... 15
  - Tissue donation and transplantation ..... 16
- Appendix B: All Governments’ Statement (June 2017) ..... 18

## Preamble

The National Eye and Tissue Sector Framework (the Framework) provides the future directions for the Australian eye and tissue sector. The Framework sets the national objectives to achieve the vision that all Australians<sup>1</sup> have safe, equitable and ethical access to life-altering and/or life-saving tissue transplantation, through a strong and effective Australian eye and tissue donation for transplantation sector.

The Framework forms the response of all Australian governments to the *Analysis of the Australian Tissue Sector*<sup>2</sup> undertaken by PricewaterhouseCoopers (PwC): (the PwC Report). It seeks to:

- acknowledge the role of the Australian eye and tissue sector in the broader health system
- support better coordination and consistency of actions across the health system to ensure continued and sustainable access to tissues and tissue-based products
- support and strengthen what currently works well in the sector
- provide flexibility to accommodate future and emerging priorities and allow for innovation
- complement and accommodate relevant state-based, national and international policies.

The Framework needs to align with the revised ethical guidelines for living and deceased eye and tissue donation for transplantation. It will be updated following the release of the revised guidelines by the National Health and Medical Research Council (NHMRC) (expected in 2022).

This Framework provides governments, the non-government sector, professional associations, health service providers, eye and tissue service providers and the community with a clear understanding of the principles for how the Australian eye and tissue sector needs to operate to support patient access to donated tissue and tissue-based products. The Framework also considers impacts of the COVID-19 pandemic on the sector.

Implementation of the Framework will be considered by all governments. Implementation needs to be considered alongside the more recent *Review of the Australian organ donation, retrieval and transplantation system Final Report*, released in early 2020. All governments remain committed to making improvements to the organ and tissue sector to the benefit all Australians.

## Acknowledgements

Many individuals and organisations have given their time and expertise to the development of the Framework. Advice from a range of subject matter experts, in particular from the Australian eye and tissue sector, informed development. All governments would like to thank organisations and individuals involved in consultations.

This Framework has been developed collaboratively by the Jurisdictional Eye and Tissue Steering Committee (JETSC), established to oversee the response to the PwC Report. The JETSC is chaired by the Commonwealth and includes state and territory health department officials and representatives from the Organ and Tissue Authority (OTA) and Therapeutic Goods Administration (TGA). The JETSC Stakeholder Reference Group, comprising a range of sector stakeholders, has provided valuable input that has supported the development of this Framework.

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<sup>1</sup> Within the Framework, 'Australians' or 'Australian patients' refers to Australian residents who are eligible to access health services in Australia.

<sup>2</sup> PricewaterhouseCoopers Report: *Analysis of the Australian Tissue Sector (2016)*  
<https://www.donatelife.gov.au/about-us/corporate-transparency/government-reports>



## Strategic Context

The Australian eye and tissue sector is the largest donation and transplantation sector in Australia, with a significantly higher number of donations and transplantations compared to solid organs.

For the purposes of the Framework, tissues and tissue-based products comprise ocular (eye), skin, musculoskeletal, cardiovascular and amniotic tissues listed as Class II and Class III within the TGA's Regulatory Framework for Biologicals.<sup>3</sup>

Eye and tissue donation facilitates the transplantation of tissue and tissue-based products that enhance and transform the lives of recipients. The ongoing generosity of those that donate, and the work of Australian eye and tissue sector, are of significant value to the Australian community.

Australia is seeing an increasing number of tissue donations and transplants of tissues and tissue-based products. In 2020, 10,817 recipients received a tissue or tissue-based product transplant from altruistic donations by 3,018 tissue donors, including 2,728 living tissue donors and 290 deceased tissue donors. This represents more than double the number of tissue graft recipients compared with 2013 (the first year that data was available).

There were 1,318 eye donors and 2,277 corneal transplants. Since 2009, more than 23,500 Australians have received a corneal transplant. The eye and tissue sector comprises all providers, manufacturers and users of tissue-based products in Australia, as well as those involved in obtaining or delivery of overseas supply where required. The work of the sector crosses over both health service delivery, in its work with clinicians to deliver tissues to consumers that support health outcomes, and manufacturing and supply of tissue products. Some stakeholders feel strongly that the provision of tissue must be recognised as part of the health care system, not as a manufacturing sector.

The sector is diverse and is undergoing rapid change. Australian tissue banks operate under a range of organisational structures and have different scopes of activity. The legislative and regulatory framework for eye and tissue donation is complex, with banking and transplantation governed by each state and territory human tissue act (or equivalent legislation), while safety, quality and efficacy of tissues and tissue products are regulated by the TGA according to the *Therapeutic Goods Act 1989*. (See [Appendix A](#) for more information about the sector.)

All Australian governments recognise the challenges presented by the diversity and pace of change in the sector, and that without a national strategic approach there is a risk that efficiency and effectiveness of the sector could be compromised. Changes in the sector include the increasing use of imported tissue from overseas commercial providers, which presents challenges for some long-standing, not-for-profit Australian tissue banks. The PwC Report sets out these challenges and recommendations for reform, as outlined below.

The development of this Framework has occurred alongside work on the response of all governments to the Review of the Australian Organ Donation, Retrieval and Transplantation System.

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<sup>3</sup> Therapeutic Goods Administration, Regulatory framework for biologicals, <https://www.tga.gov.au/regulatory-framework-biologicals>

## PricewaterhouseCoopers Report: Analysis of the Australian Tissue Sector

In June 2015, at the request of the Commonwealth and state and territory governments, PwC undertook a review of the Australian eye and tissue sector, informed by consultation with tissue banking, eye banking, government and clinical sector stakeholders.

The PwC Report's scope was limited to donated eye and tissue products for transplantation in Australia. This included ocular, musculoskeletal, cardiovascular and skin tissue.

The PwC Report found that:

- The Australian eye and tissue sector is diverse and undergoing rapid change.
- Eye tissue banking is working effectively, transparently and inclusively. Domestic supply meets current demand and the participants are well-placed to ensure that supply sustainably meets future demand.
- Tissue transplant activity has increased significantly and demand is not met locally.
- The nature of demand differs by tissue type. Understanding the supply and demand nuances of each tissue type, and accounting for this during any change, is critical to targeting the areas of greatest need while preserving the well-functioning components of the sector.
- Innovation in the development of new types of tissue for transplantation has impacted tissue availability and the structure and function of the sector.
- Awareness of the complexities associated with the changing sector is limited.

The PwC Report recommended:

**1:** Governments must recognise that the current operation of the tissue sector will not prove feasible to sustain supply to meet domestic needs over the medium to long term. This recommendation was addressed through the release of the All Governments' Statement on the PwC Report's findings ([Appendix B](#)).

**2:** A national policy framework to clearly define the guiding policy principles for the effective operation of the sector should be developed and agreed by all governments.

**3:** Sectoral reform may be required following the implementation of Recommendation 2 in establishing and embedding a clear national policy framework.

All governments, through the then Council of Australian Governments (COAG) Health Council, accepted the recommendations of the PwC Report.

On 2 June 2017, the PwC Report was published on the OTA's website, and the All Governments' Statement<sup>4</sup> on the PwC Report's findings was published on the Department of Health's website. In the statement, Commonwealth and state and territory governments acknowledged the issues identified within the sector, agreed with the recommendations presented in the PwC Report, and committed to work together to develop a national policy framework for the sector.

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<sup>4</sup> PricewaterhouseCoopers Report: *Analysis of the Australian Tissue Sector (2016)*  
<https://www.donatelife.gov.au/about-us/corporate-transparency/government-reports>

# The National Eye and Tissue Sector Framework

## Vision

*All Australians have safe, equitable and ethical access to life-altering and/or life-saving tissue transplantation, through a strong and effective Australian eye and tissue donation for transplantation sector.*

## Objectives

The vision of the Framework is supported by three high-level objectives:

1. Safe and equitable access to life-saving and life-altering tissue and tissue-based product transplantation.
2. Supply is efficient, effective, ethically sourced and appropriate, and is supported by services that optimise altruistic donation opportunities.
3. The Australian eye and tissue sector is sustainable into the future.

## Guiding Principles

The Guiding Principles support the design, development, successful and meaningful implementation of the Framework:

- **Equity** – all Australians have equitable access to tissue transplantation.
- **Access** – all Australians have access to affordable, ethically-sourced, high standard products and appropriate services.
- **Sustainability** – strategic planning and responsible management of system resources to enable continued delivery of long-term, improved health outcomes for patients.
- **Evidence-based** – rigorous, relevant and current evidence informs clinical and operational best practice, appropriate funding and governance structures.
- **Collaboration and Partnerships** – linkages and opportunities to cooperate and partner responsibly to achieve greater impacts than can occur in isolation.
- **Shared Responsibility** – all parties understand, accept and fulfil their roles and responsibilities to support enhanced health outcomes for all Australians; and
- **Accountability and Transparency** – decisions are made and responsibilities are discharged in a way that is ethical, clearly understood and accountable, and achieves best value for public resources.

## Stakeholders

The effective operation of the Australian eye and tissue sector is strongly influenced by the contributions made by a wide range of stakeholders and partners, including:

- the Australian eye and tissue sector, including public and private tissue and tissue-based product providers
- the public and private health sectors, including end-users (clinicians)
- all governments, including regulators
- professional associations
- researchers and academic institutions
- the Australian community, including eye and tissue donors and their families.

Stakeholders have shared responsibility for health outcomes through their role and contribution. Greater cooperation between stakeholders will contribute to better overall outcomes for the sector and the patients who benefit from these transplants.

## The National Framework

PwC recommended that all governments should seek to address key issues facing the sector, in effect forming the national policy framework through which the sector should operate. In response, this Framework addresses the following areas:

1. Scope
2. Purpose
3. Governance and oversight
4. Self-sufficiency, importation and exportation of tissues and tissue-based products
5. Tissue supply costs
6. Stakeholder engagement
7. Research
8. Data and reporting.

The 2007 ethical guidelines<sup>5</sup> developed by the NHMRC relating to eye and tissue donation and transplantation were considered by all Australian governments in developing the policy positions. To further strengthen the ethical guidelines for the eye and tissue sector and address recommendations in the PwC Report, the NHMRC is currently reviewing its current guidance on organ and tissue donation and transplantation.

Following the release of the updated guidance (expected in 2022), the Framework will be reviewed and updated, if required, to ensure alignment. The NHMRC's Organ and Tissue Working Committee prepared an *Interim ethical position on key issues relating to the Australian Eye and Tissue Sector* to support governments to address the PwC Report recommendations. This interim document has been taken into account in the development of the Framework.

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<sup>5</sup> <https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-organ-and-tissue-donation-and-transplantation>



# 1. Scope

Tissues and tissue-based products comprise ocular (eye), skin, musculoskeletal, cardiovascular and amniotic tissues listed as Class II and Class III within the TGA's Regulatory Framework for Biologicals.<sup>6</sup> Tissues and tissue-based products must also be listed on the Australian Register of Therapeutic Goods (ARTG) in order to be lawfully supplied in Australia.<sup>7</sup> The scope of this document may be revised in future as required, based on clinical, technological and regulatory changes.

The World Health Organization (WHO) *Principles for global consensus on the donation and management of blood, blood components and medical products of human origin*<sup>8</sup> (WHO Principles for global consensus) and the WHO *Guiding principles on human cell, tissue and organ transplantation*<sup>9</sup> (WHO Guiding Principles) set the context for Australia's international obligations in relation to eye and tissue donation and transplantation.

The definition of tissue for the purposes of the Framework is consistent with these documents. The WHO Principles for global consensus define medical products of human origin as 'substances that are derived wholly or in part from the human body and intended for clinical application', while the WHO Guiding Principles explicitly state that they do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents (collected for transfusion purposes).

The Australian eye and tissue sector encompasses all related processes and services from the identification of a potential donor to the transplantation of a tissue or tissue-based product for a suitable recipient, including:

- donor identification and assessment
- eye or tissue retrieval
- processing and/or manufacture of retrieved tissue
- product quality assurance, inventory management and distribution
- transplantation and post-operative processes including adverse event reporting
- evaluation and product development in collaboration with clinician end users.

States and territories have made significant investments in the sustainability of the Australian eye and tissue sector, to ensure access to quality tissues and tissue-based products in their jurisdictions.

The primary legislative frameworks that govern the Australian eye and tissue sector are established by each state and territory's Human Tissue Act, or equivalent.<sup>10</sup> These Acts differ by jurisdiction and in some cases have a broader definition of tissue than is used in this Framework.

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<sup>6</sup> Therapeutic Goods Administration, Regulatory framework for biologicals, <https://www.tga.gov.au/regulatory-framework-biologicals>.

<sup>7</sup> Therapeutic Goods Administration, Australian Register of Therapeutic Goods (ARTG) <https://www.tga.gov.au/artg>. Note: products provided through the TGA Special Access Scheme can be lawfully supplied in Australia without being listed on the ARTG.

<sup>8</sup> World Health Organization (WHO). 2016. *Principles for global consensus on the donation and management of blood, blood components and medical products of human origin*, EB140/18 <https://apps.who.int/iris/handle/10665/273230>.

<sup>9</sup> WHO. 2010. *Guiding principles on human cell, tissue and organ transplantation*, WHA 63.22 [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1)

<sup>10</sup> State and territory Human Tissue Acts are listed below:  
Australian Capital Territory: [Transplantation and Anatomy Act 1978](#)  
New South Wales: [Human Tissue Act 1983](#)  
Northern Territory: [Transplantation and Anatomy Act 1979](#)  
Queensland: [Transplantation and Anatomy Act 1979](#)

## 2. Purpose

All Australian governments are committed to an ethical and sustainable Australian eye and tissue sector that:

- supports Australia to be well-positioned to meet the tissue and tissue-based product needs of Australians in a safe, ethical, sustainable and cost-effective manner
- optimises potential altruistic donation opportunities to provide tissue-based products for transplantation that deliver the best evidence-based clinical outcomes for Australian patients
- supports the supply of tissue and tissue-based products to be informed by identified clinical need for specific tissues and tissue-based products
- develops and maintains partnerships and effective engagement with key stakeholders to ensure that the sector is responsive to emerging clinical trends.

These reflect the Guiding Principles set out in this Framework.

Donated eye and tissue supply should be based on identified clinical need for particular tissues and tissue-based products. Demand is identified through established clinical feedback loops and engagement is informed and supported by relevant stakeholders including professional associations and consumers.

The Australian eye and tissue sector should focus on delivering tissue and tissue-based products to meet identified patient needs. A donor's wish to donate should be fulfilled only where domestic need for a tissue or tissue-based product is identified. This means that some donations from potential tissue donors may not progress if demand for those tissues does not exist.

The development of new tissues or tissue-based products should occur in response to an identified need, and should reflect the nationally agreed principles.

## 3. Governance and oversight

Improved governance and oversight of the eye and tissue sector will support effective implementation of this Framework. All Australian governments share responsibility and accountability for having eye and tissue supplies for Australian patients when they need them. Governance and oversight arrangements should reflect this shared responsibility and accountability. Australian tissue banks vary in operation with different scopes of activity, ownership and organisational structure. The range of these arrangements is unlikely to change into the future.

Flexibility in any new governance arrangements must align with current complex policy, legislative and regulatory arrangements. These arrangements should also align with arrangements to be determined in response to the subsequently released Review of the Australian Organ Donation, Retrieval and Transplantation System. All jurisdictions are working together on a coordinated approach to support progress of the Framework at the same time as the development of a national strategy for the Australian organ donation, retrieval and transplantation system (the Strategy). This coordinated approach will include agreement by all governments to future governance arrangements and an implementation approach for both the Framework and the Strategy.

The scope of this Framework is broad covering many activities. The OTA will continue its role providing national leadership to increase deceased organ and tissue donation in hospitals through

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South Australia: [Transplantation and Anatomy Act 1983](#)

Tasmania: [Human Tissue Act 1985](#)

Victoria: [Human Tissue Act 1982](#)

Western Australia: [Human Tissue and Transplant Act 1982](#)

the DonateLife Network in strong partnership with all governments and the tissue sector as represented on the OTA's Eye and Tissue Advisory Committee (ETAC).

The OTA's ETAC comprises all Australian eye and tissue banks, professional associations and representatives of the Commonwealth Department of Health and the TGA. It is well established and facilitates collaboration and advice on new and emerging issues in the eye and tissue sector. The OTA's national leadership with ETAC enables ongoing sector collaboration and advice in the development, review and delivery of clinical practice guidelines, professional education and community awareness.

The delivery of or management of tissue banks remain the responsibility of state and territory governments, and the regulation and standards for tissues and tissue-based products remain a TGA responsibility, both working in collaboration with the clinical sector.

It will be necessary for governments to continue working together to clarify the roles and responsibilities for all stakeholders, including all state and territory governments and Commonwealth agencies such as OTA, the Department of Health, TGA, and the Australian Commission on Safety and Quality in Health Care. This will inform next steps on strengthened governance and oversight that will in turn support the Framework's Guiding Principles, of *Sustainability, Shared Responsibility, and Accountability and Transparency*.

## 4. Self-sufficiency, importation and exportation of tissues and tissue-based products

Australia has an ethical responsibility to strive to meet its population's need for human tissue and tissue products using its own resources and without the need for external assistance. This supports the Framework's Guiding Principles of *Access and Sustainability*.

Australia will aim to be self-sufficient, where possible, through the use of tissues donated and manufactured in Australia to support safe, ethical, sustainable and cost-effective provision of tissues and tissue-based products for Australian patients.

Self-sufficiency in this context would mean that Australia is able to largely meet its own needs for tissue-based products, recognising that full self-sufficiency is highly unlikely to be attainable. All Australian governments note the increasing volume of imported tissue and recognise the need to ensure suitable arrangements are in place to support ongoing local supply.

All governments acknowledge that importation of appropriately-sourced tissues or tissue-based products that are not available in Australia may be required for the treatment of some Australian patients.

Where Australia's tissue and tissue-based product needs cannot be met through locally-donated supply (for example, when national demand for a tissue-based product exceeds Australia's capacity to supply), imported tissue and tissue-based products that meet Australian requirements can be used. Where a therapeutically equivalent tissue or tissue-based product is manufactured in Australia, end-users should be encouraged to use an Australian product, where possible, noting clinicians will determine the most clinically appropriate product for their patients.

All governments recognise the need to implement more effective systems to support altruistic tissue donation. This includes increasing awareness of the possibility of tissue donation, including in situations where organ donation is not possible, but at the same time ensuring that donation activity reflects demand for tissue and what tissue banks can feasibly accommodate. There should also be consideration of appropriate resourcing for tissue donation, recognising that current resourcing and infrastructure limitations mean that donation does not always proceed even where consent has been given.

Any importation and exportation activity should occur in accordance with Australia's international obligations and standards (such as the WHO Guiding Principles<sup>11</sup>), national ethical frameworks and national and jurisdictional legislative requirements. It should also be noted that the quality, safety and efficacy of tissues and tissue-based products supplied, imported and exported is regulated by the TGA according to the *Therapeutic Goods Act 1989*.

Exportation of Australian tissues and tissue-based products is considered appropriate in situations where Australia has met its local transplantation needs and the needs of Australian patients will not be compromised. Exportation of Australian tissues and tissue-based products should occur only when donors and/or their families have been advised that the retrieved tissues may be exported and have given their informed consent.

Exported tissues and tissue-based products should only be provided to countries in certain circumstances, namely where:

- the country's national supply does not meet their local demand including in times of national disasters and other mass casualty events
- the country acts in accordance with international obligations and standards
- Australian export activity does not impinge on local tissue banking operations or patient access.

## 5. Tissue supply costs

Tissues and tissue-based products should be provided to Australian public patients at no cost to the patient. All governments recognise that in determining if tissue and tissue-based products should be available to Australian patients and reimbursed through state and territory budgets (for public patients) or through private health insurance, consideration should be given to:

- the product being included on the Australian Register of Therapeutic Goods (ARTG);
- rigorous assessment of comparative clinical effectiveness and patient outcomes; and
- cost-effectiveness and the benchmarking of benefits payable to like products.

Australian governments agree that tissue and tissue-based products made available to Australian patients should continue to be reimbursed to providers on a fee-for-service basis. While state and territory Human Tissue Acts prohibit the trading of human tissue, recovery of costs is permitted.

The WHO Guiding Principles<sup>12</sup> provide for the reimbursement of reasonable and verifiable expenses incurred through the recovery, processing, preserving, product development, quality assurance and supply of tissue is appropriate. Generation of a surplus may be ethically acceptable if the surplus is reinvested to support activity, sustainability and/or innovation in the sector. It should not be used to make payments, provide dividends or other benefits to either individuals or other parties.

Listing and benefit setting for available tissue and tissue-based products will continue through Part B of the Australian Government's Protheses List.<sup>13</sup> Under current arrangements, tissue banks apply to the Commonwealth Department of Health to have tissue or tissue-based products listed on the Protheses List, which includes determining the benefit to be paid by end-users.

Planned reforms to the Protheses List arrangements, including a review of Part B items which will investigate how to ensure items listed in Part B are assessed for comparative cost

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<sup>11</sup> WHO. 2010. *Guiding principles on human cell, tissue and organ transplantation*, WHA 63.22, [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1)

<sup>12</sup> WHO. 2010. *Guiding principles on human cell, tissue and organ transplantation*, WHA 63.22, [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1);

<sup>13</sup> <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-protheseslist.htm>

effectiveness will further support the sustainability of the sector through improved benefit setting arrangements.

All governments support the development of guidance to assist tissue banks and other providers with any new prostheses arrangements. Representatives of the eye and tissue sector will be invited to participate in the implementation of any reforms to ensure that they consider the operation of the sector.

Further, all governments agree that tissue supply arrangements should align with state-based Human Tissue Acts or equivalent legislation and ethical guidance set by the NHMRC.

The agreed position on tissue supply costs supports the Framework's Guiding Principles of *Equity, Access, Evidence-based, Sustainability, and Accountability and Transparency*.

## 6. Stakeholder engagement

All Australian governments recognise that engagement between Australian eye and tissue sector stakeholders, including engagement of governments with potential donors, donor families and patients, is vital to the ongoing viability and sustainability of the sector, and to ensure that Australians have access to clinically-appropriate tissues and tissue-based products.

Strong stakeholder engagement supports the Framework's Guiding Principles of *Shared Responsibility and Collaboration and Partnerships*. Australian governments recognise that:

- engagement between stakeholders, including the Australian community, should be coordinated, clear and consistent
- professional associations should be actively engaged through recognised governance and oversight arrangements to ensure effective clinical feedback
- development of clinical and ethical standards should be undertaken in a collaborative and inclusive manner.

All Australian governments support stakeholder engagement to deliver on the Framework. This will include engagement between governments, regulators, the OTA, professional associations, eye and tissue donors, tissue and tissue-based product providers and distributors, and end-users, including surgeons and patients.

## 7. Research

All Australian governments recognise that research and development is required to address gaps in clinical demand, be responsive to emerging new technologies, and ensure the ongoing sustainability of the Australian eye and tissue sector. An agreed position on Research supports the Framework's Guiding Principles of *Evidence-based* and *Sustainability*.

Research and development activities are central to the sector's sustainability, and can deliver technologically-advanced treatment options and improved clinical outcomes for those Australians requiring tissue or tissue-based products.

In line with the WHO Guiding Principles,<sup>14</sup> product development may be recognised<sup>14</sup> as part of the recoverable cost of delivering a tissue product.

The Australian eye and tissue sector is encouraged to pursue opportunities and seek funding to engage in research activities, by accessing research funding available in Australia. It is acknowledged there are challenges in seeking funding through competitive processes, and it is recognised there should be consideration for reinvestment in upscaling and innovation.

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<sup>14</sup> WHO. 2010. *Guiding principles on human cell, tissue and organ transplantation*, WHA 63.22, [https://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf?ua=1](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1);

Where possible, the Australian eye and tissue sector should foster collaborative partnerships with other organisations, universities or research institutes to provide a coordinated approach to research.

## 8. Data and reporting

All Australian governments recognise that an essential part of having a sustainable eye and tissue sector in Australia is the collection and analysis of data on the sector, processes and patient outcomes. All Australian governments acknowledge the expansion in recent years of available data relating to eye and tissue transplantation.

Improvements to national data and reporting will need to be done in consultation with the sector, build upon existing data sets and processes, canvass collection, manufacture, distribution and utilisation including post-transplantation outcomes and adverse event reporting.

The current lack of data relating to imported tissue, or any product containing human tissue, is recognised as a particular challenge, and addressing this is a priority for governments. Data on the importation and exportation of tissues and tissue-based products will provide a complete picture of sector activity.

All stakeholders in the Australian eye and tissue sector have a role in collecting and providing data. This includes donation agencies, tissue banks, tissue manufacturers and distributors, regulators, funders, and users of tissues and tissue-based products.

Data and reporting should be guided by an approach that:

- facilitates the use of de-identified clinical data sets to inform and drive clinical practice improvement
- meets all relevant accountability and legislative requirements, including those pertaining to security and privacy of information
- ensures openness and transparency
- provides information to governments to enable monitoring and oversight.

Data and reporting support the Framework's Guiding Principles of *Evidence-based and Accountability and Transparency*.

## Progressing the Framework

The Framework's primary purpose is to articulate the vision for the effective and efficient operation of the Australian eye and tissue sector. The Framework delivers on Recommendation 2 of the PwC Report.

All governments, as part of implementation, will (as per Recommendation 3 of the PwC Report) determine if structural reform of the Australian eye and tissue sector is necessary to deliver elements of the Framework. Further, all governments will continue to consider what is required to increase national consistency where this could benefit the Australian eye and tissue sector and the community.

All governments recognise the need for accountability through regular reporting to ensure the Framework is successfully implemented. Sector stakeholders should take the opportunity to monitor their own progress in achieving results in relevant areas.

## Ongoing Review

The Framework will be periodically reviewed as implementation is undertaken, as community needs evolve and the sector advances. Health Ministers will be updated annually on activities in the sector. This will provide the flexibility to take into account new and emerging technologies

and uses for tissues, to keep pace with the ever-changing sector. If required, the Framework will be refined to meet changing needs, environments and emerging evidence and to incorporate any amendments or revisions to referenced documents or guidance in the Framework.

## Appendices

### Appendix A – The Australian Eye and Tissue Sector

For the purposes of the Framework, tissues and tissue-based products comprise ocular (eye), skin, musculoskeletal, cardiovascular and amniotic tissues listed as Class II and Class III within the Regulatory Framework for Biologicals. The sector comprises all providers, manufacturers and users of tissues and tissue-based products in Australia, as well as supplementary and complementary overseas supply where required.

The Australian eye and tissue sector is the largest donation and transplantation sector in Australia, with a significantly higher number of donations and transplantations as compared to solid organs.

Tissue products of human origin have unique qualities that cannot easily be substituted by existing synthetic alternatives. The tissue product needs of an active and ageing Australian population are increasing and limited access to donors has supported strong industry investment in bioengineered tissue substitution and, the development of more ratio-efficient products (such as ground bone in a paste carrier). Most alternatives, such as 3D-printed skin products, are still in their infancy, and are not widely accessible.

The origin of human eye and tissue grafts means that these therapeutic goods are considered to be of an 'exceptional nature', adding unique strategic, clinical, ethical, legal, and psychosocial dimensions to their production, availability and use.

#### Legislative Framework

##### ***State and territory human tissue legislation***

States and territories provide the legislative framework for eye and tissue donation and transplantation and tissue banking through each human tissue act or equivalent in their jurisdiction.

While there are variations between the legislation in each jurisdiction, these broadly state that there will be no trade in human tissue, and provide for the retrieval of tissue for banking and transplantation with appropriate consent. The costs that can be recovered for tissue collection and distribution are also addressed. There have been calls for harmonisation of state and territory legislation to provide greater national consistency.

##### ***Therapeutic Goods Administration (TGA)***

The safety, quality and efficacy of tissues and tissue-based products are regulated by the TGA under the Regulatory Framework for Biologicals, which requires compliance against the Code of Good Manufacturing Practice, Therapeutic Goods Orders and inclusion on the Australian Register of Therapeutic Goods (ARTG). These requirements apply to all sponsors/manufacturers whether they are located domestically or overseas or whether they are for-profit or not-for-profit entities.

The TGA assesses regulatory compliance and licenses tissue banks to manufacture tissue and tissue products for clinical use. However, primary responsibility for product safety and efficacy rests with providers of tissues and tissue-based products.

The ARTG is administered by the TGA and is the comprehensive list of human-derived tissue products that can be accessed for clinical applications in Australia. To include a product, tissue providers (including international entities) must submit a product dossier to the TGA which makes an assessment of the quality, safety and clinical efficacy of a product.



The *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*<sup>15</sup> (the AOTDTA Act) established the Australian Organ and Tissue Donation and Transplantation Authority, also known as the Organ and Tissue Authority (OTA).

It is a statutory agency under the Commonwealth Government Health portfolio and is responsible for implementing the national reform agenda on organ and tissue donation for transplantation, in partnership with the states and territories, clinicians, consumers and the community. The AOTDTA Act sets out the functions of the OTA for both organ and tissue donation and transplantation matters.

## Eye donation and transplantation

Eye donation aims to preserve or restore sight through the transplantation of corneas and sclera in oculoplastic reconstructive surgery.

There are five eye banks operating in Australia, operating either on a stand-alone basis (Lions Eye Donation Service Victoria, Lions Eye Bank of WA, South Australia Eye Bank) or incorporated into multi-tissue banking health department structures (Queensland Tissue Bank incorporating the Queensland Eye Bank, NSW Tissue Banks incorporating the Lions NSW Eye Bank). All Australian eye banks are not-for-profit and maintain close or formal links with research institutes, universities and end-users.

Eye banks are usually located within or close to the hospital that undertakes the majority of eye tissue transplantation in their state, an arrangement which also allows close engagement with end-users (ophthalmologists). Eye banks act as donor coordination services (with the exception of the Lions Eye Bank of WA where this function is undertaken by DonateLife WA). This includes donor referral and identification, donor testing and evaluation, and consent.

All eye banks undertake surgical retrieval, manufacture and distribution of ocular tissue. Although each bank largely focuses on regional supply, non-competitive and networking arrangements between all eye banks ensure supply across all jurisdictions.

Potential eye tissue donors can be identified through various arrangements within the community, hospitals and the coronial system. Close collaboration and donation partner arrangements with DonateLife agencies and hospital-based organ and tissue transplantation coordinators have had a positive impact on the rate of eye tissue donation, and have contributed to demand in Australia being met successfully.

The retrieval of eye tissue is performed by eye bank staff, as a 'bedside' procedure. Exceptions to this include retrievals undertaken in regional areas, the Australian Capital Territory (ACT) and Tasmania. In these instances retrieval is performed by local medical, nursing or mortuary staff trained in the procedure.

There is a national feedback loop on outcomes via the national Australian Corneal Graft Registry, which provides clinical data on corneal transplant outcomes such as graft survival, visual acuity, rejection rates and indication for transplant.

Data on eye donor numbers and supplied grafts is currently collected and reported by the Australia and New Zealand Organ Donation Registry on a monthly basis. The Eye Banking Association of Australia and New Zealand also collects an extended eye donation and transplantation data set for quality and safety and service improvement purposes.

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<sup>15</sup> *Australian Organ and Tissue Donation and Transplantation Authority Act 2008*, <https://www.legislation.gov.au/Latest/C2017C00206>

## Tissue donation and transplantation

A number of different types of tissues, other than ocular tissue, are donated for processing and graft manufacturing by Australian tissue banks:

- *skin* – used as biological, sometimes life-saving, dressings for burns
- *musculoskeletal tissue (MSK)* – bone used for structural reinforcement repair post-trauma, following cancer resection, or as fillers in dental surgery; ligaments and tendons used in sports injury repair; muscular fascia may be used as reinforcements in neurological, gynaecological and abdominal surgery
- *cardiovascular tissue* – heart valves used in valve replacement surgery, blood vessels as conduits for vascular reconstructions<sup>7</sup>, or pericardium used as reinforcement materials
- *amniotic membrane* – used for ophthalmic surgery and as a wound treatment.

Australian tissue banks operate under a range of organisational structures and scope of activity, as follows (all information is correct at the time of publishing and may be subject to change):

New South Wales (NSW):

- NSW Tissue Banks (public, not-for-profit, multi tissue donation and retrieval: MSK, skin, eyes and amniotic membrane)
- Hunter New England Bone Bank (public, not-for-profit, bone from femoral head (FH) and distribution of other NSW tissue and tissue-based products)
- Sydney Heart Valve Bank (public, not-for-profit, cardiac tissue)
- Rachel Forster Bone Bank (public, not-for-profit, bone from FH only)
- Australian Biotechnologies (private, for-profit, contracted manufacturer/distributor, MSK)
- Australian Tissue Donation Network (ATDN) (private, not-for-profit, bone from FH procurement agency)

ACT:

- DonateLife ACT (public retrieval of cardiovascular tissue when organ donation is occurring)

Queensland:

- Queensland Tissue Bank (public, not-for profit, in the process of amalgamating the Queensland Heart Valve Bank, the Queensland Eye Bank and the Queensland Bone Bank, which is licensed for MSK and skin manufacture)

South Australia:

- South Australia Bone Bank (public, not-for-profit, bone from FH only)

Victoria:

- Donor Tissue Bank of Victoria (public, not-for-profit, multi tissue: MSK, skin, cardiovascular tissue)
- Barwon Health Bone Bank (private, not-for-profit, bone from FH only)

Western Australia:

- PlusLife (private, not-for-profit, MSK)

Living bone donation is the most common pathway for bone donation in Australia. It commonly occurs as part of hip replacement surgery when a patient consents to their femoral head to be donated, rather than the tissue being discarded. However the cost-benefit of bone donation is low, both in terms of poor quality tissue and overall yield.

Tissue retrieval is usually performed by local tissue bank technical staff, as there is the requirement for medical professionals to perform the retrieval.

The private not-for-profit ATDN independently identify, screen, approach for consent and perform tissue retrieval. In NSW all retrieved MSK tissue is referred to Australian Biotechnologies for processing and distribution.

Supply from a tissue bank occurs following requests received from (end-user) surgeons. A single bank may offer various types of tissue grafts both within its jurisdiction and across jurisdictional borders depending upon supply and demand.

Although most tissue banks have clear channels of communication with end-users, feedback is needed between banks and end-users that would enable better understanding of tissue availability, outcomes, demand and trends in surgical practice, which lags behind that of eye banks.

Data on tissue donor numbers and supplied tissue and tissue-based products is currently collected and reported by the Australia and New Zealand Organ Donation Registry on a monthly basis.

However, this data collection is limited and has scope for improvement. In addition, data on tissue transplantation resulting from importation or from a specific Special Access Scheme request is not reported.

## Appendix B: All Governments' Statement (June 2017)

In June 2015, at the request of the Commonwealth and State and Territory governments, PricewaterhouseCoopers undertook an Analysis of the Australian Eye and Tissue Sector. The report from the analysis presents an overview of the eye and tissue sector, as informed by stakeholders in tissue banking, government and clinical sectors.

The eye and tissue sector is the largest donation and transplant sector in Australia. Each year the lives of thousands of Australians are transformed through the transplantation of generously donated eyes and tissues.

The report found that the Australian eye and tissue sector is diverse and undergoing rapid change in some areas. There was a 350 percent increase in tissue transplant activity in Australia over the 2009-2014 period and the pace of growth and change continues. As a result of this growth, the local availability of tissues for transplantation has not always met the community's needs. As in other areas of the health sector, innovation in the development of new types of tissue for transplant has had a significant impact on the availability of tissue for transplant and the structure and function of the Australian sector. The report also found that awareness of the emerging complexities associated with the changing sector is limited. To ensure the continued adequate supply of tissue to meet the transplantation needs of the Australian population further work is required to support the sector in meeting these challenges to ensure the availability of eyes and tissues for transplantation in Australia into the future.

The Commonwealth and State and Territory governments acknowledge that there are some issues within the sector which require rapid action. We agree with the recommendations presented in the report, particularly Recommendation Two which identifies that there is a need for a national policy framework for the sector that is agreed between all governments. This will inform the implementation of other measures to ensure the continued availability of eyes and tissues for those Australians who need them. The Commonwealth and State and Territory governments will work together to develop this national policy framework.

The Governments recognise that the eye and tissue sector is complex with multiple stakeholders. In addressing the recommendations within the report the Government will engage with key stakeholders to ensure that issues identified in the report can be addressed in a meaningful way to ensure the Australian eye and tissue sector is sustainable into the future.

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All information in this publication is correct as at August 2022

