Australian Law Reform Commission: Review of the Human Tissue Laws

Joint response from the **Biotherapeutics Association of Australasia (BAA)** and the **Eye Bank Association of Australia and New Zealand (EBAANZ).**

July 2025.

Submission Response

Definitions

For this submission response, we use the terms:

> **'Substances of Human Origin' (SHO)** to collectively describe human biological donations from living and deceased donors. Our definition includes both regenerative and non-regenerative donations, including but is not limited to tissues (musculoskeletal, (bones and tendons), heart valves, eyes (cornea and sclera), skin and amnion), cells, bloods, microbiome, and human milk.
>
> **'Use' (usage):** to collectively refer to the potential end use of the SHO across transplantation (e.g., corneal transplantation); injection/infusion (e.g., blood); ingestion (e.g., milk and microbiome) and use in service validation, training, and research.

Overview

With a rapidly changing and increasingly complex donation and allocation environment, the Biotherapeutics Association of Australasia (BAA) and the Eye Bank Association of Australia and New Zealand (EBAANZ), welcome the commencement of the Human Tissue Law Review, as identified in Issue Paper 51 (May, 2025) published by the Australian Law Reform Commission.

Those working in this field support donors, donor families, recipients, and researchers to help improve access to healthcare services today and in the future. As such, they have frontline knowledge of the complexities involved, and the undeniable need for harmonisation and up-date of the jurisdictional Acts, and associated reform, to meet the expectations of the National Eye and Tissue Framework (2022) and the expected outcome from the Commonwealth working group's review. The reform must also be underpinned by Australian contemporary societal expectations and values.

While the subtleties of each Act must be evaluated, in essence the key elements of the review must centre around addressing issues experienced today, and those anticipated to increase in the future. These pertain particularly to profit, commodification, commercialisation, SHO movement across jurisdictions, importation into Australia, the transition to future therapies (e.g., cellular injections) and the emergence of biotech actors in the space.

In Australia, the practice of SHO banking has also changed over the last 35 years with some organisations moving away from the traditionally perceived model which assumes a bank is recovering, processing, storing, and allocating, under one manufacturing license with singular medical oversight within one corporate structure. In reality, some banks may perform only one or

two of those functions. It is within this split model that different jurisdictional Acts have been interpreted differently by some organisations resulting in commodification of some SHOs.

With the introduction of biotech, which is exploring for example, bioengineering, the Acts must also include these actors under the same legal expectations and ethical frameworks. While the revised Acts must not hinder medical and scientific advancement or prevent the advancement of the Australian biotech industry, it must ensure they are aligned with the legal and guiding ethical principles. Meaning, all actors, from traditional to non-traditional to biotech must be held to the same legal and ethical standards.

While changes to the Acts must not hinder the advancement of the field and those working in it, by ensuring there is scope for their service sustainability into future therapies and cellular therapies – as this is where the field is moving and may offer better outcomes for waiting recipients, the Acts must ensure that such advancement does not derail long term donor access. Meaning, organisations involved in the donation, processing, commodification, and/or allocation, must do so ethically and transparently, otherwise this may compromise long term willingness of donors to donate and in turn derail access to donations.

The non-traditional banking model and advent of biotech actors and investors in this space, who may not be as familiar with the Acts and other guiding documents as the traditional banks are, also increase the likelihood of 'advertising' SHOs. While there is a need to inform end users of their options, to ensure they can make an informed decision that is the best fit for their recipient/use, and providers (banks, distributors) must, for example, be allowed to outline their services on their website and present their outcomes in sector presentations and papers. The review must carefully consider where the lines are drawn in terms of inappropriate advertising and/or aggressive and/or predatory marketing and promotional tactics. This needs to be clearly defined to assist all actors engaged in the space and to ensure donors can be reassured that their donation is not denigrated by inappropriate promotion that seeks to influence rather than inform decision making of donors, next of kin/guardians, surgeons, researchers, and recipients.

Advertising must also be considered in terms of its general impact on raising awareness with the Australian community about their options to become a donor during life and at the point of their death. The Acts must ensure organisations involved in the sector can raise awareness within jurisdictions, but the Acts must also provide guidance on the limitations in terms of appropriateness. This is important because donation numbers are dropping across Australia, and the sector must have a mechanism to help increase donation (and registration). This will then impact those waiting for the SHO. Advertising or awareness raising is one mechanism to support sustainable future donation. Another mechanism is consistent consenting models for SHO donation across jurisdictions and SHO types.

The Acts must harmonise to recognise the cross-jurisdictional movement of donations, to meet need, which is a necessary function in Australia (and practiced in other countries) to ensure the donation reaches its appropriate end use. This also ensures the donation is not wasted. Reform should support promotion of donation across all jurisdictions equally to ensure the ethical sourcing practices for the collection and use of a SHO in Australia is consistent across all jurisdictions. In doing so however, the harmonisation must not allow for actors working outside of the ethical and legal framework to move donated SHO between jurisdictions independent of use. Ethical frameworks for the custodianship of donated SHO should be considered to extend to the management of the SHO until it is allocated for use. Reform must not reduce the security of a jurisdiction's existing tissue donation, processing and allocation services for another

jurisdiction that may have ethical frameworks that are not aligned with the aims and principles proposed in the Issues paper.

The reform must ensure non-therapeutic (non-transplant/injection/infusion/ingestion) use is included in the Acts. Such use includes allocation to research, training, and service validation (validation is a requirement of the Therapeutic Goods Administration - TGA). The reform must allow for the sector to recover and allocate for these purposes on the proviso that the consent and management is in line with the relevant NHMRC guidelines and other guidance frameworks. Providers must be allowed to recover the costs from these uses.

Finally, the reform must not only protect the donations from unethical use, but it must also protect the sector by ensuring it has the chance to flourish (growth, job creation, development, providing the latest and best therapeutics etc.) by ensuring, for example, that imports are not undermining the sustainability of the domestic sector. Imports in and of themselves must be checked, not only by the TGA for their medical suitability but also by another governing arm, to ensure the donations are sourced from ethically validated providers and their imports are transparently reported, from the point of donation to use.

Response to the Commission's Questions

1. What is your personal experience of how human tissue is obtained or used in Australia?

Response

BAA and EBAANZ members are organisations and professionals that work within the sector that will be impacted the most by changes to the Acts that are under review by the Australian Law Reform Commission (Issue paper 51).

BAA and EBAANZ are not-for-profit organisations, and the peak Australian bodies for SHO. Their members are responsible for donor identification and suitability, family donation conversations, consent authorisation, recovery, processing and allocation of SHOs, towards the range of potential end 'uses' as well as managing quality assurance and research aspects of the service. Their members act as the Custodians of the donation. They steward the donations to their intended use, as consented by the donor and/or their Senior Available Next of Kin (SANOK)/guardian.

They provide national and international leadership and standards development across a range of donation and allocation areas, advocating for the SHO banking sector by promoting the unique requirements of SHO banking, and facilitating the sharing of information and expertise amongst members. Representatives from both organisations sit on the Australian Organ and Tissue Authority's Eye and Tissue Advisory Committee and Clinical Governance Committee as well as the Commonwealth working group and various international steering groups.

Representatives from both organisations sit in the unique juncture of the human biologicals field, nestled between donors, many of which are end-of-life, and the end user – including those waiting for a transplant. They hold the donor and their donation with the utmost regard and respect, recognising that without the donor and/or their SANOK/guardian, recipients will not receive access to the donation,

surgeons will not be trained, and research to prevent and treat a range of conditions will not advance.

2. What is your personal experience of how human tissue laws work in Australia?

   Response

   As a professional body, BAA and EBAANZ assist members working on the front-line, that are working under their own jurisdiction's Act. Overwhelmingly, members report of challenges, for example, the definition of what a 'donation agency' is. This term is not consistent. For example, it is not consistent in defining who can legally facilitate consent for donation across jurisdictions, SHO types and use. In the context of the national distribution of a SHO between jurisdictions, and agency types, consistency and transparency in the legal instruments that guide the sector are required to support the sector going forward. The impact of this inconsistency challenges the sector's ability to successfully sustain services, particularly for non-profit agencies, and/or gain support from other agencies, government and other interested groups (e.g. from research grants and philanthropists).

   Members agree that the reform must also address limitations in the Acts, to support future sector advancements. For example, cellular therapies, as there is currently a lack of clarity on the definitions which may create challenges for actors including donation agencies, researchers, traditional banks, other providers, and biotech.

3. When we think about the laws governing how human tissue is obtained and used, what are good aims or objectives for these laws?
   You might think about aims such as:
   a. increasing the amount of tissue available for transplantation and/or other uses;
   b. creating a transparent and easy to navigate tissue donation system;
   c. making sure tissue donation happens safely;
   d. making sure people have a good understanding of what is involved in donating
   e. tissue;
   f. making sure people understand how their tissue will be used;
   g. equity, and removing barriers faced by some individuals or groups to human tissue
   h. donation or transplantation;
   i. making sure how human tissue is obtained and used is consistent with respect for
   j. persons and the human body.

   Response

   BAA and EBAANZ agree with these suggestions, and add the following additional objectives of:
   a. increasing the amount of ethically sourced SHOs; and
   b. creating a transparent and easy to navigate system for all stakeholders.

4. When we think about reforming human tissue laws, what principles should guide reform? You might consider principles such as:
    a. respect for persons and for the human body;
    b. equity;
    c. the importance of public trust in the framework that governs how human tissue is
    d. obtained and used in Australia;
    e. the importance of laws that are well designed and effective.

    Response

    BAA and EBAANZ support these suggestions.

    If the SHOs are to align into a scaffold of social confidence they will also need to demonstrate proactive, intervention-based enforcement capabilities, rather than a latent or investigatory function.

5. Do you agree that the issues set out in the section 'Priority reform areas' should be a focus for our Inquiry? Please tell us about why you think these issues should or should not be a focus.

    Response

    BAA and EBAANZ agree.

6. What, if any, other issues should we be focusing on in this Inquiry?
    You might think about areas where improvements in the law would be easy; or areas where law reform might be difficult but still important, because the current law is not working well. You might also think about:
    a. if there are issues caused, or likely to be caused, by current or emerging technology that we haven't identified in this Issues Paper; and
    b. if there is a need to update the HTAs to account for contemporary community values, in ways that we haven't identified elsewhere in this Issues Paper.

    Response

    Other issues for consideration are:
    a. The current laws do not consider demand for future therapies and the mechanisms and funding models that would support the availability of tissue for future health care improvement. Consideration might be given to how an ethical framework for this could be developed.
    b. Is 'tissue' the correct catch all phrase for these Acts? As per recent changes in the EU, the term 'Substance of Human Origin' – as we use here in our submission response, appears to better reflect what these Acts are trying to encompass. Other terms such as 'human biologicals' may also be considered.
    c. The review needs to consider how the Acts interact with the regulations across the SHOs and the accuracy of the term 'tissues' in this context. For example, cells are not tissues. There may also be confusion between where new services, like microbiome, sit within the human biological framework,

and others, like human milk, which is a SHO, and is currently classified as food and regulated as food not a human biological.

d. There is also a clear difference between how organs and organ donors and services are treated and managed in comparison to SHOs. This needs to be considered. For example, organs remain under the remit of a health service model and are managed and maintained as non-profit services. In comparison, SHO providers, which receive less support, are subject to TGA and Good Manufacturing Practice (GMP) requirements, which, while important, increases the costs and complexities of the SHO management and increases the time period to provide new SHO types to waiting Australians. They must also navigate the 'medical device' field and register their SHO on the Australian Register of Therapeutic Goods and in turn work with other services, such as the Prescribed List, and manage the recouping of costs for their service. As 'products' (a term used by the TGA) are becoming more complex, e.g. combined products, then the SHO provider is subject to greater requirements than those providers in the organ space.
   The different approach between organs and SHOs has also resulted in the actual and latent creation of 'financial value' of some SHOs, by those seeking to commodify, commercialise and profit. To highlight this point, we propose that there would be community outrage if there were for-profit actors preparing to commodify and profit from an organ donation. This would never be allowed, and yet the current Acts inadvertently allow for this to occur in the SHO space.
   The treatment of the donor and the donations, regardless of it being organ or not must be standardised with SHO placed with equal importance, urgency and societal value as organs.
e. The Acts should also harmonise to ensure non-therapeutic use, e.g. research/training, are supported. The current system, which focuses mainly on therapeutic use only, tends to screen out donors that would be valuable for researchers and trainees. This denies opportunity for informed decision making by donors and/or their SANOK/guardian and limits the chance to fulfill the donor's wish of donating for the future advancement of medical care.
f. The revised Acts must also consider how the SHO Acts interact and/or override the current Privacy Act. This is because the SHO Acts are jurisdictional while the Privacy Act is federal, and because organisations involved in this field must move donors and donations between different partner organisations. This is a routine and essential function of the sector. Organisations need to be able to confidentially share some donor details in order to manage the donation safely and effectively. Similarly, this needs to be considered in terms of recipient management too, e.g. to perform basic billing and scheduling functions. It needs to be developed to allow the services to practically identify/de-identify (a linked system) across all the various donation uses and across a services partner transfers.
g. The review would also benefit from evaluating the legal, ethical and practical implications of allowing (or not allowing) a donor's SANOK/guardian to override the donor's wishes. This needs to be considered in terms of the potential distress it might cause to the living SANOK of a deceased donor, if the system were allowed to override (or not override), in comparison to the implications of dishonouring the donor and how that might impact future

donor willingness and the willingness of SANOK's to participate in altruistic donation.

h. Finally, some jurisdictions prevent non-medical practitioners from recovering donations such as tissues. This is not practical for the development of sustainable services within the jurisdiction where this is the case. Globally, donors who donate SHOs like tissues are routinely consented, recovered and managed by trained nurses and other allied health staff with a medical/bioscience background.

7. Are there inconsistencies between the HTAs that we have not identified in this Issues Paper that are causing problems and should be a reform focus for us?

Response

a. Not necessarily in the HTAs (SHO) but the references and examples in Issue Paper 51 pertain to organs. For the review to be successful, the next discussion paper must use non-organ examples and references.
b. There is inconsistency within the jurisdictional Acts in terms of what they consider a 'tissue' to be.
c. The review's follow-up discussion paper would benefit from a comparative Act table to assist readers to determine the differences, similarities and gaps.
d. The discussion paper may also benefit from determining if Acts should or should not include the full range of SHOs as we define, or if these should be separated. Regardless, the Act/s must include scope for clinical therapeutic use (transplant/infusion/ingestion), training (including anatomical training), validation use (to validate new services), and biobanking (research allocation – both laboratory use and human-in-animal use).

8. Do you think it is important that we consider any of the issues in the section 'Issues we are unlikely to focus on in this Inquiry'? If so, why?

Response

BAA and EBAANZ agree that they should be reviewed separately.

Other: With the advent of Artificial Intelligence (AI) a separate review must also consider if, how, where and when the sector can use AI. It may be an inevitable evolution that will be beneficial to services, but it must be considered and implemented without causing actual or perceived harm to donors, SANOK/guardians, the community and more over the individuals engaged in providing the service. It must also be considered in relation to the Privacy Act.

BAA and EBAANZ representatives are available to assist the Commission with their review and welcome the opportunity to meet to discuss further and participate on the Review's working panel group. We can be contacted via info@ebaanz.org.

On behalf of our members, thank you for this opportunity.

Regards

Chris van Diemen (BAA Chair)

Pierre Georges and Dr Heather Machin (EBAANZ co-Chairs)