Submission to the Review of Australia's Human Tissue Acts

Introduction

Stem Cell Donors Australia and ANZTCT welcome the opportunity to contribute to the review of Australia's human tissue legislation.

Stem Cell Donors Australia is Australia's only stem cell donor registry, having been established over 30 years ago as a not-for-profit charity funded by Commonwealth and State jurisdictions. We are proud to support Australian patients in need of life-saving bone marrow, blood stem cell and cord blood transplants (collectively, hematopoietic stem cells or HSCs) who are unable to find a suitable donor within their family.

The Australia and New Zealand Transplant and Cellular Therapies (ANZTCT) Ltd is the peak professional body for bone marrow transplant and cellular therapies in Australia and New Zealand. Established as a not-for-profit organisation, ANZTCT brings together clinicians, scientists, nurses, pharmacists, and other professionals dedicated to advancing safe, equitable, and high-quality care in haematopoietic stem cell transplantation and cell and gene therapy. Through its leadership in clinical standards, research, education, and policy development, ANZTCT supports innovation and collaboration to improve outcomes for patients undergoing life-saving transplant and cellular therapies.

Stem cell transplantation is uniquely distinct from organ and tissue transplantation. It requires a distinct regulatory framework that supports international exchange, donor protection, and recipient access. We urge the Australian Government to preserve the stem cell transplantation exemptions and arrangements that have proven effective, while modernising the legislation to accommodate evolving clinical practices, technologies, and ethical considerations.

Our submission is confined to considerations relevant to the donation and transplantation of HSCs from donors who are not also the recipient. While our focus is donors who are unrelated to the recipient, there are also several issues with respect to genetically related donors that are relevant and have been discussed below.

Stem Cell Donors Australia's current exemption from the Human Tissue Acts (HTAs) by State Ministers of Health, has enabled Australian participation in an efficient and ethically-governed international network of stem cell donor registries. Australia's ongoing access to this global network is vital to saving Australian lives. Currently, 80% of Australian patients that require an unrelated donor transplant depend on an overseas donor to provide their life-saving HSC; and the overseas donor registry being able to recover their costs for this supply. Australia's access to these overseas donors is based on reciprocity - overseas registries must be able to access Australian donors when required for their patients. To ensure that this access is moderated, we ensure financial reciprocity – we recover our costs of supply through charging overseas registries when accessing Australian donors, the price they would charge us. This ensures that Australian Donors are not utilized because we might charge a lower price than for use of a nation's own

donors. Any amendments to the HTAs must ensure that these arrangements are preserved and strengthened.

Key Considerations

1. Useful Definitions

Define "blood stem cells" to include hematopoietic stem cells derived from bone marrow, peripheral blood and cord blood.

Distinguish between:

- Donations made by the intended recipient for their own use ('autologous' donation) from donations made by a consenting individual to benefit another ('allogeneic' donation)

- Allogeneic donations can be further categorized as being from donors that are 'related' or 'unrelated' to the intended recipient. Both have unique implications relevant to HTAs.
[Note that unrelated donors in this context are only those who proceed to donation, and not the individual registrants who have joined our registry as potential donors.]

- Allogeneic donations can be further categorized as 'directed' donations (made for a specific recipient) and 'non-directed' donations (processed for potential future or multiple use, as is the case for cord blood or some cell and gene therapies).

2. Scope and Application

Maintain current exemptions under HTAs (and Therapeutic Goods Regulations[1]) for directed, unrelated donor donations coordinated by the Registry, to safeguard Australia's participation in international exchanges from where more than 80% of Australian HSC transplants are currently sourced.

Consider the evolving nature of genetic relatedness in directed related donations. Because of technical advances in managing partially matched HSC transplants, it is decreasingly the case that related donation occurs where the donor is a first-degree relative of the recipient, and therefore the donation is unarguably in the best interests of the donor as well as the recipient. Increasingly distant family members (even minors) are being requested to donate, some of whom have never met the recipient.

Consider the use of donated material for research purposes. It is not uncommon for part of a donation – sometimes all the donation, if the patient unexpectedly deteriorates - to be unused. Cord blood units are also sometimes requested for research purposes. This research may or may not be transplantation-related.

Consider also the emerging nature of cell and gene therapies. It is feasible that donated material could be processed into products made available for use by one or multiple future recipients. These products could

[1] Exempt blood stem cell transplantation from TGRs consistent with the exemption for organ transplants, recognizing the urgent, minimally-processed nature of these therapies

be made available by public research institutions or private commercial entities. A framework for donor protections, rights and regulations should be considered.

Consider future issues relating to donor rights with regards to subsequent genetic testing of donated cells. What are the donor's rights if subsequent genetic testing of the recipient identifies an adverse genetic issue of donor origin? It is generally accepted, today, that future genetic testing of the donor carries no obligation to inform the recipient of any adverse outcomes.

3. Donor Consent and Protection

a. General Provisions

- Free, informed, and documented consent for all donors covering all intended uses of their donated material
- In all cases, prohibit coercion or financial gain, and allow reimbursement of legitimate donor and donor registry expenses, noting the importance of the not-for-profit status of the registries today.
- Donations should be authorised by a physician independent from any role in care of the recipient and supported by independent counselling, consent and follow-up processes.
- Ensure transparency around how the entirety of the donation is used, particularly in research and emerging cell therapies.

b. Child and Non-Competent Donors

- Prohibit donation by minors or non-competent individuals except in limited, regulated circumstances:
  - Recipient is a first-degree relative.
  - No other suitable donor is available.
  - It is in the donor's best interest.
  - Independent oversight (e.g. court or regulatory approval) is in place.

c. Unrelated Donors

- Donations should be facilitated by the national registry, where it is subject to accreditation and ethical oversight.
- Acknowledge patient-recipient anonymity may only be preserved temporarily. Existing processes allow for donor-recipient contact from 2 years post-transplant. It is of critical importance for some unrelated donors to be able to have the ability to connect to their recipient, should they consent.

d. Related Donors

- Should have in place additional ethical considerations where there is an elevated risk of coercion or pressure, especially for a child or non-competent donor.

4. Directed vs Non-Directed Donations

Directed donations:

- Require documented evidence of the medical necessity of the donation.
- Confirm the donor is the most appropriate available option.

- Requires authorisation by the national registry (for unrelated donors).
- Documentation of how any remaining material will be used or disposed.

Non-directed donations (e.g. cord blood):
- Require documented consent and transparency in intended use cases, including research or manufacture.

5. International Exchange

Explicitly permit the import and export of blood stem cells for therapeutic and research purposes.

Permit cost recovery and reciprocal pricing for products and services facilitated by the national registry.

6. Prohibitions and Offences

Prohibit:
- Commercial trading in blood stem cells (noting emerging commercial cell and gene therapy market).
- Coercion or exploitation of donors against their best interests.
- Misrepresentation of intended use of donations.

Permit responsible advertising and promotion to recruit individuals to join the unrelated donor registry, and promote the importance, risks, and benefits of voluntary blood stem cell donation.

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