Johnson&Johnson

Johnson & Johnson Family of Companies, ANZ
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Australian Law Reform Commission
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Submission to the Australian Law Reform Commission (ALRC) – Review of Human Tissue Laws (Discussion Paper 90, 2025)

By electronic lodgment

23 January 2026

Dear Commissioners,

The Johnson & Johnson Family of Companies in Australia ("J&J") welcomes the opportunity to provide feedback on the Australian Law Reform Commission ("ALRC") Review of Human Tissue Laws: Discussion Paper 90 (2025). The Johnson & Johnson Family of Companies in Australia comprises Johnson & Johnson Medical Pty Ltd representing the medical technology business and Janssen-Cilag Pty Ltd, a research based pharmaceutical company. J&J is a diversified healthcare organisation with global operations in medical technology, innovative medicines, and biological and regenerative product development. Our portfolios include multiple human tissue–derived therapies.

We strongly support the ALRC's objective to create a modern, consistent, ethical, and innovation-supportive national human tissue framework. At the same time, we believe some of the proposed reforms, particularly those relating to the prohibition of trade, paid donation restriction, advertising restrictions and importation requirements, require refinement to avoid unintended consequences for patients, clinical trials, and Australia's biomedical sector.

Below, we outline key considerations for the Commission.

1. Need for Explicit Exemptions Covering ARTG-Registered Products, SAS Access, and Clinical Trials (Proposal 42, Q36, Q40)

J&J strongly supports the principle behind Proposal 42—that the prohibition on trade should not apply to therapeutic goods that have been assessed and approved by the Therapeutic Goods Administration ("TGA") or accessed lawfully via Special Access Scheme ("SAS") or clinical trials.

However, as drafted:

- Clinical trials are not clearly captured, and
- It is unclear whether exemptions apply to both autologous and allogeneic products, including those derived from paid donors in overseas jurisdictions.

Recommendation:
The exemption should be drafted to explicitly cover:

1. Any human tissue–derived therapy included on the Australian Register of Therapeutic Goods ("ARTG"), including pharmaceuticals, biologics and medical devices/technologies.
2. Any human tissue–derived therapy supplied via the SAS (Category A, B, or C).
3. Any human tissue–derived therapy used within a Clinical Trial (CTN/CTX) approved under the *Therapeutic Goods Act* (1989) ("TG Act").
4. All donor types (paid and unpaid; autologous and allogeneic; domestic and international).

The explicit inclusion of clinical trials avoids unintended regulatory burdens for clinical trial sponsors, investigators, hospitals, ethics committees, and tissue suppliers. Without this clarity, approved clinical research using tissue-derived products, including autologous cell therapies,

allogeneic scaffolds, regenerative matrices, and emerging "off-the-shelf" cell therapies, may become needlessly encumbered.

2. Recognition That Paid Donor Tissue Is Essential for Many Current and Future Therapies (Question 36)

The ALRC asks in Question 36 whether exemptions should apply to enable paid plasma donation. J&J respectfully submits that the scope must be broader than plasma. There are existing and developing products managed by different ARTG sponsors that may rely on paid donor tissue due to the scarcity of un-paid donor tissue for important and life-saving therapies, including:

- Biosurgery haemostatic products
- Allograft-based human tissue products and/or medical devices
- Next-generation cell therapies.

Paid donation is regulated in major markets such as the United States, where blood, tissue, and cell donation systems rely on donor compensation. Australia already imports plasma-derived medicinal products (PDMPs) from paid US donors due to domestic shortfalls[1].

Recommendation:
The "paid donor exception" should be expanded to **all forms of human tissue that contribute to a regulated therapeutic good that is approved and listed on the ARTG**, not limited to plasma. Narrowly scoping may unintentionally restrict Australian patient access to innovative.

3. The "No Profit" or "Cost Neutrality" Concepts in Q40 Are Not Fit for Purpose

Question 40 raises whether a mechanism is needed to ensure that tissue-derived therapies imported into Australia were obtained "without reward or profit". For industry stakeholders, including J&J, this concept poses significant practical and policy challenges for several reasons:

- **The therapeutic supply chain necessarily relies on commercial, for-profit entities.** Critical functions, including donor screening and testing, GMP-compliant manufacturing, cold-chain logistics, and distribution, are performed by commercial organisations whose operations cannot be structured on a cost-recovery basis.
- **Cost-neutral pricing is inherently unsustainable.** The costs associated with producing and supplying human-tissue-derived therapies (manufacturing, quality assurance, regulatory compliance, pharmacovigilance, and global distribution) increase over time. A rigid cost-neutrality requirement would restrict the ability of manufacturers to absorb rising costs and remain viable.
- **Prohibiting profit would deter innovation.** Advanced therapeutics, including cell, gene, and tissue-based products, require substantial investment in R&D, manufacturing capability, and regulatory processes. A "no profit" framework would deter innovators from supplying these products in Australia, ultimately working against the public interest and reducing patient access to transformative treatments.

Recommendation:

If the ALRC adopts a clear exemption pathway through ARTG inclusion, SAS authorisation, or clinical trial (CTN/CTX) approval, as suggested in our earlier submission, there is no need for safety and efficacy regulation and these products should be exempt from any supplementary 'no-profit' or 'no reward' mechanism. Compliance with Australia's therapeutic goods regulatory framework provides an appropriate and robust safeguard.

[1] https://www.abc.net.au/news/2024-07-07/donating-blood-plasma-money-red-cross-supply/103923554 [Accessed 24 Jan '25]

Such an approach appropriately targets the policy objective, ensuring ethically sourced material, while enabling a functioning and innovative therapeutic sector capable of delivering safe, effective, and high-quality treatments to Australian patients.

4. Advertising Restrictions (Proposal 45)

We recommend that the ALRC expressly clarifies that the advertising prohibitions in human tissue legislation do not apply to otherwise lawful and compliant communications regarding therapeutic goods listed on the ARTG, including biologicals and medical devices.

The current proposal creates uncertainty and risks unintentionally capturing routine, non-promotional activities that are essential to the safe and effective use of these therapies and otherwise compliant with TG Act and associated regulations.

As outlined in our prior submissions (dated July 2025) educational, clinical, and instructional materials provided to healthcare professionals have been previously caught in existing State and Territory Human Tissue Act and Regulations. These materials are fundamental to ensuring appropriate product selection, safe handling, correct administration, and overall quality use of therapeutic goods, each of which is central to patient safety. Therefore, an advertising exemption for products listed on the ARTG is necessary to:

- prevent duplication and conflict between Commonwealth therapeutic-goods regulation and state/territory human-tissue advertising prohibitions;
- maintain nationally consistent rules governing clinical communications, rather than creating fragmented state-based restrictions;
- ensure patient safety by allowing clinicians timely access to product-specific information that supports correct use, appropriate handling, and informed treatment decision-making; and
- support innovation and access by ensuring that human-tissue-derived therapies are not disadvantaged by regulatory ambiguity or inconsistent communication barriers across Australia.

Such clarification will preserve the integrity of advertising prohibitions aimed at preventing commercialisation of human tissue, while avoiding unintended barriers to clinical education and safe product use.

5. Support for National Consistency and TGA Alignment

We echo industry feedback that the TGA is the logical regulator for therapeutic products derived from human tissue. A fragmented regulatory environment (e.g., involving both a new National Regulator and the TGA) would impose unnecessary complexity and cost.

Conclusion

J&J supports the ALRC's goal of a modernised, ethical, and nationally harmonised human tissue framework. We welcome the opportunity to continue engaging with the ALRC as the Final Report is developed.

Yours sincerely,
Johnson & Johnson Family of Companies, Australia