Human Tissue and Transplant Amendment Bill 2022

EXPLANATORY MEMORANDUM

The Human Tissue and Transplant Amendment Bill 2022 (the Bill) amends the *Human Tissue and Transplant Act 1982* (the Act) to provide a modern regulatory framework that provides for a broad range of tissue supply contracts and arrangements and supports access to future advancements in biological medicines and technologies. The Bill aligns, where appropriate, with existing National and State processes for tissue supply to reduce the regulatory burden on industry and Government.

The Bill also makes consequential amendments to the *Anatomy Act 1930* and *Health Legislation Administration Act 1984.*

The Bill is set out as follows:

PART 1 – Preliminary

Clause 1 **Short title**

The Act will be called the *Human Tissue and Transplant Amendment Act 2022*.

Clause 2 **Commencement**

This clause provides for the commencement of the Act, with Part 1 coming into operation on the day on which the Act receives the Royal Assent.

Part 2, Divisions 1 and 2 and Part 3 will come into operation on the day after Assent. Part 2 Division 3 will come into operation on a day fixed by proclamation, and different days may be fixed for different provisions.

PART 2 – *Human Tissue and Transplant Act 1982* amended

Division 1 – Preliminary

Clause 3 **Act amended**

This clause provides that Part 2 of the Bill amends the Act.

Division 2 – General amendments

Clause 4 **Long title replaced**

The clause deletes the long title of the Act and replaces it with a more concise description that removes references to outdated legislation and captures the new power to remove tissue for training, education and quality assurance purposes.

Clause 5 **Part 1 heading amended**

This clause amends the heading to Part 1 to reflect modern drafting practice.

Clause 6 **Section 3 amended**

This clause inserts definitions for "human egg", "human embryo" and "human sperm" into section 3(1) of the Act for the purposes of section 6. These terms are as defined in the *Human Reproductive Technology Act 1991*.

Clause 7 **Section 4 amended**

This clause amends section 4 to include gender neutral terminology and reflect modern drafting practice.

Clause 8 **Section 5 amended**

This clause amends section 5 to include gender neutral terminology and reflect modern drafting practice.

Clause 9 **Section 5A inserted**

This clause inserts a section 5A into the Act to provide a modern framework for the delegation of the Minister's powers or duties under the Act.

Clause 10 **Part II heading amended**

This clause amends the heading to Part 2 to reflect modern drafting practice.

Clause 11 **Section 6 replaced**

This clause updates the terms used in the definition of "tissue" for the purposes of Part 2. This includes inserting "human embryo" into the definition, as the *Human Reproductive Technology Act 1991* also regulates the donation of human embryos.

Definitions for the terms "human egg", "human embryo" and "human sperm" are included in section 3(1) of the Act.

Clause 12 **Section 8 amended**

This clause amends section 8 to include gender neutral terminology and reflect modern drafting practice.

The clause also amends section 8 to provide that consent may be given to the removal of regenerative tissue, other than blood from a person's body, for training, education and quality assurance purposes in relation to therapeutic purposes or medical or scientific purposes.

Clarifying the scope of therapeutic purposes or medical or scientific purposes, to include training, education and quality assurance purposes will allow consent to be provided under the Act for the removal, and use, of tissue to support training and quality assurance processes for pathology services. This purpose is also relevant to the changes that have been made to sections 15, 18, 22, 24 and 28.

Clause 13 **Section 15 amended**

The clause amends section 15 to provide a medical practitioner has authority to remove from a person's body, in accordance with a consent given under section 8, regenerative tissue, other than blood for training, education and quality assurance purposes in relation to therapeutic purposes or medical or scientific purposes.

Clause 14 **Section 18 replaced**

This clause deletes section 18 and replaces it with a new section 18 which includes gender neutral terminology and reflects modern drafting practice.

The clause provides that in addition to the existing purposes in section 18, consent may also be given to the removal of blood, or any of its constituents, from a person's body for training, education and quality assurance purposes in relation to therapeutic purposes or medical or scientific purposes.

Clause 15 **Section 19 amended**

This clause is a consequential amendment to address the changes to section 18.

Clause 16 **Part III heading amended**

This clause amends the heading to Part 3 to reflect modern drafting practice.

Clause 17 **Section 21A inserted**

This clause inserts a new section 21A into the Act.

Section 21A clarifies that Part 3 of the Act does not apply to the removal of tissue for the purposes of the practice of anatomy under the *Anatomy Act 1930*.

The Anatomy Act regulates the removal, but not the sale and supply of tissue for the practice of anatomy. The introduction of "for teaching, education and quality assurance" as a "permitted purpose or use" in the Act has the potential to confuse the distinct aspects between the two Acts where tissue is to be removed for the practice or teaching of anatomy.

Clause 18 **Section 22 amended**

The clause amends section 22(1) to provide authority for a designated officer for a hospital to authorise the removal of tissue from a body of a person who has died in hospital, or whose dead body has been brought into the hospital for training, education and quality assurance purposes in relation to therapeutic purposes or medical or scientific purposes.

Clause 19 **Section 24 amended**

Clause 19(1) deletes section 24(1) and inserts new subsections (1), (1A) and (1B).

New subsection (1) inserts two new definitions into the Act in respect to who is a "permitted practitioner" for the purposes of section 24 and what is a "permitted purpose or use" for the purposes of section 24.

Whilst “permitted practitioner” is a newly defined term, it captures the same persons identified in previous section 24(1)(a).

“permitted purpose or use” is a newly defined term. It includes the same purposes identified in previous section 24(1)(c) and (d) of the Act and adds a third purpose, for the use of the tissue for training, education and quality assurance purposes in relation to therapeutic purposes or medical or scientific purposes.

New subsection (1A) provides that in addition to permitted practitioners, other authorised and appropriately trained technicians, appointed under new section 24A, may remove skin and musculoskeletal tissue in addition to ocular tissue from deceased persons for a permitted purpose or use.

Removal of skin and musculoskeletal tissue in addition to ocular tissue from deceased donors can be performed safely by appropriately trained technicians in the absence of a medical practitioner. This change supports the safe, timely and efficient removal of tissue and reduces the loss of potential donor tissue which may occur when a medical practitioner is not available.

New section 24(1A)(d) provides that the retrieval or use of fresh, viable organs for direct donor to recipient transplantation, are still required to be retrieved by a permitted medical practitioner. This is an existing requirement in the Act.

New subsection (1B) provides that an authority under Part 3 of the Act is subject to any restrictions that apply to that authority by reason of section 22(3). This is an existing requirement under the Act.

Clause 19(2) is a consequential amendment arising from the new definition of a “permitted purpose or use”.

Clause 19(3) deletes section 24(4). New section 24A provides for who is an authorised person for the purposes of section 24(1A).

Clause 20 **Section 24A inserted**

This clause inserts a new section 24A into the Act.

Section 24A replaces previous section 24(4) of the Act. It provides a modern framework for the appointment of authorised persons by the Minister for the purposes of section 24(1A).

A savings provision is also included in new section 24A(4) to provide continued authority for persons previously authorised under section 24 to remove tissue for corneal transplantation, to be able to remove ocular tissue for a permitted purpose or use.

Clause 21 **Part IV heading amended**

This clause amends the heading to Part 4 to reflect modern drafting practice.

Clause 22 **Section 28 amended**

The clause amends section 28(2) to provide authority for tissue removed from a person's deceased body, as part of a post-mortem examination to be used for training, education and quality assurance purposes in relation to therapeutic, medical, teaching or scientific purposes.

Clause 23 **Part V heading replaced**

This clause replaces the heading to Part 5 to reflect the changes to the trading in tissue provisions in the Act.

Clause 24 **Part VA heading amended**

This clause amends the heading to Part VA to Part 6 to reflect modern drafting practice.

Clause 25 **Part VI heading amended**

This clause amends the heading to Part VI to Part 7 to reflect modern drafting practice.

Clause 26 **Section 33 amended**

The clause makes consequential amendments to reflect modern drafting practice, align with the changes made to section 18 and clarify the interaction of the Act with the *Anatomy Act 1930*.

Clause 27 **Section 37 inserted**

This clause inserts a new section 37 into the Act.

New section 37 expands on existing section 35 of the Act which allows the Governor to make regulations under the Act. Section 37 provides the ability for the Governor to make regulations which adopt, in whole or with modification, other regulatory instruments such as Codes or other subsidiary legislation.

For example, this provision could be used to adopt the *Therapeutic Goods Act 1989* (Cth) Prostheses List Part B, which uses a cost recovery model for its pricing structure, as a potential component for an authorised supplier to use in determining its cost recovery amount.

Clause 28 **Various references to gender removed**

This clause amends various provisions within the Act to include gender neutral terminology.

Clause 29 **Other minor amendments**

This clause amends various provisions within the Act to reflect modern drafting practice.

Division 3 – Amendments relating to trading in tissue

Clause 30 **Section 3 amended**

This clause inserts a definition of "Human Tissue Advisory Body" into section 3(1) of the Act. This term is used in new sections 29B(2), 29E(3)(b) and 29F.

This clause inserts a definition of “therapeutic goods” into section 3(1) of the Act. This term is used in sections 29A(4)(d) and (e) and 29B(1)(a).

This clause inserts a definition of “Therapeutic Goods Act” into section 3(1) of the Act. This term is used in section 29A(4)(e) and in the definitions of “TGA provision” in section 29A(1) and “authorised supplier” in section 29B(1).

Clause 31 **Section 29 replaced**

Clause 31 deletes section 29 and inserts new sections 29, 29A, 29B, 29C, 29D, 29E and 29F into the Act.

New **section 29** clarifies that Part 5 of the Act does not apply to the sale or supply of a human embryo, human sperm or a human egg.

The *Human Reproductive Technology Act 1991* regulates the sale and supply of a human embryo, human sperm or a human egg.

New **section 29A** provides for the prohibition on the trading of tissue except in specified circumstances.

Subsection (1) inserts definitions for “exempt entity” and “national product price list” for the purposes of section 29A(4).

Subsection (2) provides that unless allowed under sections 29C, 29D(1) and 29E a contract or arrangement providing for either the sale or supply of human tissue from a person’s body, or the post-mortem examination or anatomical examination of a person’s body after death, for valuable consideration is void.

Subsection (3) provides it is an offence if a person enters into a contract or arrangement of the kind to which subsection (2) applies. The penalty for this offence is 12 months imprisonment or a fine of $12,000. This penalty is intended to reflect the seriousness of the offence and act as a deterrent.

Subsection (4) provides that subsection (2) does not apply to the following sale and supply contracts and arrangements relating to tissue:

- Contracts or arrangements providing only for the reimbursement of any expenses necessary incurred by a person in relation to the removal of tissue is accordance with the Act. This is an existing exemption under the Act to the prohibition against trading in section 29A(2).
- contracts or arrangements for the supply of blood products (including fresh blood products, and plasma derived products, and includes a number of products sourced from overseas) on the National Product Price List (NPPL).
- contracts or arrangements for the sale or supply of tissue by an “exempt entity”, where the sale or supply is carried out by or with an exempt entity or the Commonwealth for the benefit of an exempt entity, and the tissue is the subject of an agreement between the exempt entity and the Commonwealth or State.

An “exempt entity” is defined in subsection (1) as an entity prescribed by the regulations that is a party to an agreement with the Commonwealth or the State for the sale or supply of tissue. For example, the Australian Bone Marrow Donor Registry, which manages donations from suitable blood and marrow stem cell donors for patients in need of haemopoietic stem cell transplants, is proposed to be prescribed as an exempt entity under the regulations.

- contracts or arrangements for the sale or supply of therapeutic goods that are comprised, contain or derived from tissue (biologicals, biological medicines and combination products) that have been authorised or approved under the TGA and Special Access Scheme (SAS) and Clinical Trials Scheme (CTS).

  The SAS and CTS under the TGA have a number of pathways, but in general enable access to ‘unapproved’ therapeutic goods not on the Australian Register of Therapeutic Goods, where a prescribing health practitioner considers use of the therapeutic good clinically justified, after consideration of benefits and potential risks for an individual patient.

- Contracts or arrangements providing for the sale and supply of tissue where the sale and supply of the tissue meets the requirements in section 29B(3).

Subsection (4)(a) – (d) cater for contracts and arrangements that may not necessarily meet the requirements set out for “authorised suppliers” under new section 29B, however are considered essential human tissue supply arrangements for modern medical practice. Aligning with existing national supply processes avoids undue administrative burden and ensures clinical care is not impacted.

Subsection (5) provides that nothing in section 29A renders inoperative a consent or authority given under the Act in relation to tissue from the body of a person, if a person acting in pursuance of that consent or authority did not know and had no reason to know that the tissue or the body was subject to an unauthorised contract or arrangement. This is an existing provision under the Act.

New **section 29B** relates to the exemption in section 29A(4)(f). This section provides requirements for “authorised suppliers” to recover certain costs involved in supplying a tissue product.

Subsection (1) inserts a definition of “authorised supplier” into the Act to mean:

(a) a person who supplies therapeutic goods that comprise, contain or are derived from tissue; and are included in the Register under the *Therapeutic Goods Act 1989* (Cth) (the TGA) or a registered goods under the TGA;

Examples of human tissue products to which section 29B (1)(a) would apply include, bone and tendon grafts, corneal transplant grafts, skin grafts and implants developed from human tissue donated in Australia, or from international suppliers able to comply with the requirements of subsection (3).

(b) a person who owns or control a tissue bank.

A "tissue bank" is defined as a facility that is established for the purposes of the removal, evaluation, processing, storage and distribution of tissue and is prescribed in the regulations.

It is proposed that a number of human donor milk banks which provide pasteurised human donor milk for supply to vulnerable preterm infants will be prescribed under this provision. Subsection (2) provides that regulations prescribing a facility as a tissue bank cannot be made unless the Human Tissue Advisory Body established under section 29F has recommended the making of the regulations; and the Minister for Health has approved the recommendation.

This further level of approval ensures the sale and supply of processed and treated human tissue is ethical and appropriately regulated by legitimate approved tissue banks.

Subsection (3) outlines the requirements for the permissible sale and supply of tissue by an authorised supplier for the purposes of section 29A(4)(f). These include that the human tissue has first been provided or supplied through altruistic donation (i.e. not for valuable consideration), the tissue has been subject to processing and treatment and is being sold or supplied for use for a specified purpose outlined in subsection (3)(d). The consideration that may be given to an authorised supplier is restricted to those costs necessarily incurred by the authorised supplier in relation to the removal, evaluation, processing, storage and distribution of the tissue.

Subsection (4) provides regulations may set out the components of a cost-recovery amount for authorised suppliers or otherwise regulate the charging of the cost recovery amount.

New **section 29C** provides the power for authorised schools of anatomy to recover costs involved with the supply of donated cadaveric material within WA and in relation to inter-jurisdictional transfers within Australia.

This is essential for anatomical teaching, specialist surgical training and medical research in WA.

Subsection (1) provides that an "authorised school of anatomy" for the purposes of this section is as defined under the *Anatomy Act 1930.* A definition of "donated body" is also included to clarify that section 29C relates only to bodies of deceased persons received or possessed by an authorised school of anatomy in accordance with the *Anatomy Act 1930*.

Subsection (2) provides for the circumstances in which an authorised school of anatomy may charge an amount to recover the costs associated with the supply of a donated body or portion or specimen part of a donated body. Permitted circumstances include:

- where the supply arrangement is to another authorised school of anatomy;
- where the supply arrangement is to a person to whom section 18 of the *Anatomy Act 1930* applies;
- inter-jurisdictional transfers between authorised schools of anatomy across Australia.

Subsection (3) outlines what constitutes “reasonable costs” for the purposes of subsection (2).

Subsection (4) clarifies that the prohibition outlined in section 29A(2) does not apply to the contracts or arrangements referred to under section 29C(2).

It is important to distinguish that section 29C enables cost recovery in respect to existing supply arrangements authorised under the *Anatomy Act 1930*. It does not permit the entering into of cadaveric material supply contracts or arrangements not presently authorised under the *Anatomy Act 1930*.

New **sections 29D** and **29E** provide powers for the Minister for Health to ensure proper oversight of the new trading in tissue provisions under Part 5 of the Act.

Section 29D provides for the power for the Minister to make an Order as to the application of section 29A.

Subsection (1) provides the power for the Minister to make an Order declaring that section 29A(2) does not apply to the sale or supply of a class or classes of products derived from tissue that has been subject to processing and treatment. This replaces an existing power in previous section 29(4) of the Act which provided a similar power to the Governor in Council.

Subsection (2) provides a new power for the Minister to make an Order declaring that a specified contract or arrangement or class of contract or arrangement that may otherwise fall within one of the permissible sale and supply arrangements under section 29A(4), is void.

This power to veto an otherwise authorised contract or arrangement, recognises that, while national regulatory processes such as those provided through the TGA are robust, these processes are generally focussed on product safety and quality; national assessment of supply arrangements may not extend to the provenance of tissue. Breaches of international legislation, and ethical concerns relating to live and deceased human tissue donation practices outside of Australia have arisen from time to time, and this new power will offer an additional safeguard for tissue supply arrangements.

Subsection (3) provides that an Order made under subsections (1) and (2) may include conditions.

Subsection (4) provides that the Minister may amend or revoke an Order made under subsections (1) and (2).

Subsection (5) provides a savings provision for any Orders previously made by the Governor in Council under previous section 29(4).

Section 29E provides for the Minister to approve certain contracts and arrangements.

Subsection (1) provides that the Minister may in writing if considered desirable by reason of special circumstances, approve the entering into of a contract or arrangement that would otherwise be void under section 29A(2).

Subsection (2) provides that section 29A(2) or (3) does not apply to a contract or arrangement where the Minister has approved that contract or arrangement under subsection (1).

Subsection (3) provides requirements for which the Minister must comply with prior to approving the entering into a contract or arrangement under subsection (1).

Subsection (3)(a) is an existing requirement and relates to contracts or arrangements in respect to non-regenerative tissue for the purposes of transplantation into the body of a living person. For example, this provision is used to allow arrangements approved by the Minister under the Australian and New Zealand Paired Kidney Exchange Program.

Subsection (3)(b) is a new power to enable the Minister to approve, upon the recommendation of the Human Tissue Advisory Body the entering into other contracts or arrangements where valuable consideration may or may not have been given.

Where local supply is not available, a case by case arrangement for the importation from overseas of cadaveric material, either fresh, frozen or plastinated, for teaching, education or scientific purposes or anatomical examination could be a possible contract or arrangement that may be considered for approval by the Minister under this provision.

Providing for the Minister's approval to be contingent on the recommendation of the Human Tissue Advisory Body, safeguards against the potential for ministerial abuse of the powers of discretion and allows for additional scrutiny of the contract or arrangement. The Ministerial approval under section 29E(3)(b) does not, however, extend to contract or arrangements for the retrieval or use of fresh, viable organs for donor-to-host organ transplantation. It will remain an offence to trade fresh, viable organs for monetary payment or reward.

New **section 29F** provides a regulatory framework for the establishment of a Human Tissue Advisory Body.

Subsection (1) provides the Human Tissue Advisory Body is to be established via an instrument signed by the Minister for Health.

Subsection (2) provides that the instrument must identify the members of the Advisory Body or their manner of appointment; the length and conditions of appointment; the duties and responsibilities of the Advisory Body and its members and any other matters in relation to the constitution, operation and procedures of the Advisory Body that the Minister considers appropriate.

Subsection (3) provides that the Minister may amend or revoke an instrument establishing the Advisory Body.

Subsection (4) provides that the Advisory Body may determine its own procedures.

Subsection (5) provides that any remuneration and allowances paid to members of the Advisory Body may be determined by the Minister on the recommendation of the Public Sector Commissioner.

This Advisory Body will be responsible for making recommendations to the Minister regarding tissue banks to be prescribed in the regulations as an "authorised supplier" in accordance with section 29B(2)(a) and the entering into tissue supply contracts or arrangements in accordance with section 29E.

As an example, the Advisory Body may consider matters such as the provenance of tissue, whether a donation has been a paid or altruistic donation, and the regulatory environment in which a tissue supplier operates, to inform its recommendations.

Clause 32 **Section 30 amended**

Clause 32(1) inserts a penalty of imprisonment for 12 months or a fine of $12,000 for an offence under section 30(1).

This penalty is intended to reflect the seriousness of the offence and act as a deterrent.

Clause 32(2) inserts a new subsection (2) into section 30 to enable the Minister for Health to approve in writing certain advertisements or classes of advertisements relating to the buying in Australia of human tissue or of the right to take tissue from the bodies of persons.

The promotion of voluntary, non-remunerated blood donation by the Australian Red Cross Lifeblood, to ensure the supply of blood products in Australia, is an example of a class of advertisement that could be approved in writing by the Minister.

PART 3 – Consequential amendments

Clause 33 ***Anatomy Act 1930*** **amended**

Clause 33(1) provides that section 33 amends the *Anatomy Act 1930*.

Clause 33(2) deletes section 20(c) of the *Anatomy Act 1930* and inserts a new section 20(c) which updates the reference to the repealed *Tissue Grafting and Processing Act 1956*.

The heading to section 20 of the *Anatomy Act 1930* has also been updated to reflect this change.

Clause 34 ***Health Legislation Administration Act 1984*** **amended**

Clause 34(1) provides that section 34 amends the *Health Legislation Administration Act 1984*.

Clause 34(2) amends section 9(7)(a) of the *Health Legislation Administration Act 1984* to provide that the Minister cannot utilise section 9(1) of that Act to delegate any of the Minister's powers or duties under the *Human Tissue and Transplant Act 1982*.