

## HUMAN TISSUE AND TRANSPLANT AMENDMENT BILL 2022

### *Introduction and First Reading*

Bill introduced, on motion by **Ms A. Sanderson (Minister for Health)**, and read a first time.

Explanatory memorandum presented by the minister.

### *Second Reading*

**MS A. SANDERSON (Morley — Minister for Health)** [12.25 pm]: I move —

That the bill be now read a second time.

The Human Tissue and Transplant Act 1982, the act, provides for the removal of human tissue for transplantation, for other therapeutic purposes, for medical and scientific purposes and for post-mortem examinations. Since the introduction of this act, there have been revolutionary changes in biological technologies and substantial growth in the range of medical products derived from human tissue. These therapeutic goods supplied through local, national and international trade arrangements have been essential in the practice of modern medicine. The act's current general prohibition for trading of human tissue products is based on proposals that were adopted from the 1977 Australian Law Reform Commission's seventh report, *Human tissue transplants*, and is no longer fit for purpose.

The bill I present today will provide a refreshed regulatory framework for a broad range of existing tissue supply contracts and arrangements, and will support access to future advancements in biological medicines and technologies. The bill will align with the existing national and state processes for tissue supply to reduce the regulatory burden on industry and government.

I now turn to the key elements of the bill. The bill is broken up into three parts. Part 1 provides for the short title and commencement of the bill. As some of the bill's provisions will require regulations to be brought into effect, part 2, divisions 1 and 2, and part 3 of the bill will come into effect on the day after royal assent. The rest of the bill will come into effect on a date set by proclamation, and different days may be fixed for different provisions. It is anticipated that work on these regulations will commence following the bill's passage through Parliament. Part 2 provides for the amendments to the Human Tissue and Transplant Act 1982. This is the substantive part of the bill. Part 3 provides for minor consequential amendments to the Anatomy Act 1930 and the Health Legislation Administration Act 1984.

Firstly, the bill will expand on the types of tissues that may be removed by non-medical practitioners. The bill will allow, in addition to medical practitioners, other authorised and appropriately trained technicians to remove skin and musculoskeletal tissue in addition to ocular tissue from deceased donors for transplantation or other specified purposes. Removal of these tissues from deceased donors can be performed safely by appropriately trained technicians in the absence of a medical practitioner, and is usual practice in a number of other jurisdictions. 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.

Secondly, the bill will allow certain authorised suppliers to recover the costs involved in supplying a human tissue product for specified purposes when the human tissue has been first provided or supplied through altruistic donation—that is not for valuable consideration—and has been subject to processing and treatment. The term “authorised supplier” is defined in the bill to mean a person who supplies therapeutic goods that comprise, contain or are derived from tissue and are included in the register or are registered goods under the commonwealth Therapeutic Goods Act 1989, the TGA; or a person who owns or controls a tissue bank prescribed in the regulations. For example, as donor human milk is considered a human tissue under the act, this will allow costs to be recovered by prescribed tissue banks supplying pasteurised donor human milk for vulnerable preterm infants in Western Australia.

Thirdly, the bill will allow for other important supply arrangements for human tissue products that may not necessarily meet the requirements set out for authorised suppliers, but are essential human tissue supply arrangements for modern medical practice. For example, some international human tissue products may not be processed from altruistically donated tissue or limited to a cost-recovery amount. These types of sale and supply arrangements include: contracts or arrangements for the supply of blood products, including fresh blood products and plasma-derived products, and including a number of products sourced from overseas, on the National Product Price List; 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 government 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 the bill 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; and contracts or arrangements for the sale or supply of therapeutic goods that comprise, contain or are derived from tissue—biologicals, biological medicines and combination products—that has been authorised or approved under the Therapeutic Goods Administration, the special access scheme and the clinical trials scheme.

Fourthly, the bill will allow authorised schools of anatomy, as defined in the Anatomy Act 1930, to recover costs involved with the supply of donated cadaveric material within WA and in relation to interjurisdictional transfers within Australia that are authorised under the Anatomy Act 1930. This is essential for anatomical teaching, specialist surgical training and medical research in WA.

Fifthly, the bill provides new powers for the Minister for Health to ensure proper oversight of these new trading arrangements. These include, firstly, where special circumstances exist, the ability for the minister to approve certain contracts or arrangements that would otherwise be void under the new regulatory framework. The minister's approval in this regard will be contingent upon the recommendations of a new advisory body, known as the human tissue advisory body. This approval power does not, however, extend to contracts 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.

The new human tissue advisory body will also provide recommendations to the minister regarding the prescribing of tissue banks as authorised suppliers in the regulations. Secondly, the bill also provides a new power for the Minister for Health 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 the new regulatory framework to be void.

This power to veto an otherwise authorised contract or arrangement recognises that, although national regulatory processes such as those provided through the TGA are robust, these processes are generally focused 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 Australia have arisen from time to time, and this new power will offer an additional safeguard.

Other components of the bill include updates to the terms used in sections 3 and 6 of the act to ensure consistency with the Human Reproductive Technology Act 1991; updates to include gender-neutral terminology throughout the act; amendments to clarify that tissue may be removed and used for education, training and quality assurance relating to a therapeutic, medical or scientific purpose; provision for the Minister for Health to approve 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; provision for delegation of the minister's powers or duties under the act; provision for regulations to adopt, in whole or with modification, other regulatory instructions such as codes or other subsidiary regulation; increases to the penalties for trading and advertising relating to trading in human tissue; and amendments to clarify 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 sale and supply of human tissue is a sensitive and complex issue. It is important to stress that the need to uphold ethical principles ensuring donors are not exploited, that respect is shown for both living and deceased individuals, and that the human body is not treated as a commodity to be sold for profit, has underpinned the development of the bill. The bill therefore aims to support access to lifesaving and life-enhancing human tissue and tissue products for patients in need, whilst ensuring the sale and supply of human tissue is ethical and appropriately regulated.

Pursuant to Legislative Council standing order 126(1), I advise that this bill is not a uniform legislation bill. It does not ratify or give effect to an intergovernmental or multilateral agreement to which the government of the state is a party; nor does this bill, by reason of its subject matter, introduce a uniform scheme or uniform laws throughout the commonwealth.

I commend the bill to the house.

Debate adjourned, on motion by **Mr P.J. Rundle**.