

Human Tissue and Anatomy Legislation Amendment Bill 2003

Explanatory note

This explanatory note relates to this Bill as introduced into Parliament.

Overview of Bill

The objects of this Bill are as follows:

- (a) to allow tissue lawfully removed from the body of a living person for the purposes of medical, dental or surgical treatment to be used for other therapeutic, medical or scientific purposes only with the consent of the person from whom the tissue was removed or, if the person has died, a senior available next of kin,
- (b) to allow tissue to be removed from the body of a deceased person and used for therapeutic, medical or scientific purposes only with the written consent of the deceased person (given during his or her lifetime) or the consent of a senior available next of kin (so that a lack of objection by those persons will no longer be sufficient to authorise the procedure),
- (c) to allow a post-mortem examination of a deceased person to be conducted, in non-coronial cases, only with the written consent of the deceased person (given during his or her lifetime) or a senior available next of kin (so that a lack of objection by those persons will no longer be sufficient to authorise the procedure),
- (d) to allow tissue removed from the body of a deceased person for the purposes of a post-mortem examination to be used for other therapeutic, medical or scientific purposes only with the written consent of the deceased person (given during his or her lifetime) or a senior available next of kin,
- (e) to make further provision with respect to the prohibition against entering into certain contracts or arrangements relating to the sale or supply of human tissue,
- (f) to make it clear that anatomical examination includes any use of any human body for scientific or medical purposes, or educational purposes connected with medicine or science, and to require any such anatomical examination to be conducted only by a licence holder under the *Anatomy Act 1977*,
- (g) to allow the anatomical examination of the body of a deceased person to be conducted only with the written consent of the person (given during his or her lifetime) or of a senior available next of kin (so that a lack of objection by those persons will no longer be sufficient to authorise the procedure),
- (h) to make it an offence to conduct an anatomical examination of a human body except with the appropriate authority under the *Anatomy Act 1977*,
- (i) to prohibit a person consenting to or authorising the removal of tissue from the body of a deceased child who was in the care of the State, or the postmortem examination or anatomical examination of such a deceased child,
- (j) to require regard to be had to the dignity of a deceased person in the conduct of all post-mortem examinations and anatomical examinations,
- (k) to make further provision with respect to transfer and disposal of bodies that are retained for anatomical examination,
- (l) to authorise the retention or use of human tissue removed from the body of a deceased person, without explicit authority from the deceased person or a next of kin, in certain specific circumstances (such as where a small sample of tissue is retained in the form of a tissue block or tissue slide),

(m) to confer more substantial enforcement powers in connection with the provisions of the *Human Tissue Act 1983*,
(n) to confer additional regulation-making powers under the *Human Tissue Act 1983* and the *Anatomy Act 1977*,
(o) to make other miscellaneous and consequential amendments and amendments of an ancillary nature.

Outline of provisions

Clause 1 sets out the name (also called the short title) of the proposed Act.

Clause 2 provides for the commencement of the proposed Act.

Clause 3 is a formal provision giving effect to the amendments to the *Anatomy Act 1977* set out in Schedule 1.

Clause 4 is a formal provision giving effect to the amendments to the *Human Tissue Act 1983* set out in Schedule 2.

Clause 5 is a formal provision giving effect to the amendments to the Acts referred to in Schedule 3.

Schedule 1 Amendment of Anatomy Act 1977

Meaning of “anatomical examination”—extension of activities for which a licence is required

The amendments make it clear that the expression *anatomical examination* of a dead human body extends to the use of a body for medical or scientific purposes, including carrying out any procedure on the body, or subjecting the body to any experiment, process or research for medical or scientific purposes (or educational purposes associated with medicine or science). Accordingly, anyone who proposes to use dead human bodies for such purposes will require a licence under the *Anatomy Act 1977*. See **Schedule 1 [1], [2], [5]–[8], [12], [16], [17] and [24]. Schedule 1 [23]** includes a savings provision.

An anatomical examination will not include a post mortem examination that is required or directed by a competent legal authority or authorised under the *Human Tissue Act 1983*. A licence will not be required in order to conduct such an examination. See **Schedule 1 [4]**.

Authority to conduct anatomical examination

At present, a designated officer for a hospital may authorise the anatomical examination of the body of a deceased person if it appears that the deceased person had (during his or her lifetime) consented to that action or it appears that the deceased person had not (during his or her lifetime) expressed an objection to that action and a senior available next of kin has not objected to that action.

Under the amendments, a designated officer will be permitted to give such an authority only if the deceased person (during his or her lifetime), or a senior available next of kin, consents in writing to the anatomical examination.

The amendments will also allow a designated officer for a forensic institution to give such an authority in the same circumstances.

Any anatomical examination must be conducted in accordance with the relevant authority.

See **Schedule 1 [9]–[11]. Schedule 1 [1]** includes consequential amendments.

Conduct of anatomical examinations

The offences in the Act are revised so as to make it clear that:

- (a) anatomical examinations must be conducted at licensed premises, and
- (b) anatomical examinations must be conducted by licence holders or persons authorised by licensed holders, and
- (c) anatomical examinations must be conducted in accordance with an authority that, under the Act, is sufficient to authorise the conduct of the anatomical examination.

Anything authorised by or under the *Coroners Act 1980*, the *Human Tissue Act 1983* or any other law is excluded from the above offences. See **Schedule 1 [17]**

and [18].

In addition, it will be an offence to give an authority under the Act without having made the inquiries that the person is required by the Act to have made.

See **Schedule 1 [17]**.

The amendments also make it clear that anatomical examinations are to be conducted having regard to the dignity of the deceased person. See **Schedule 1 [20]**.

Transfer of human tissue

The amendments allow a licence holder to transfer human tissue (that is, an organ or other part of a dead human body) to another licence holder, an authorised officer for a hospital or interstate hospital or any other person approved by the Director-General of the Department of Health. Details of the transfer must be registered, and arrangements must be made for the return and disposal of the human tissue. See **Schedule 1 [13]**.

Disposal of bodies

At present, the *Anatomy Act 1977* requires a body of a deceased person that is retained for anatomical examination to be disposed of within 4 years after the death of the person. However, an inspector may authorise the retention of a body for a longer period.

The amendments will limit the discretion of an inspector to grant such an authorisation. In particular, an inspector will not be able to authorise the retention of a human body, or a part of the body, for more than 8 years after the death of the person.

The amendments also extend the disposal requirements to any human tissue that is removed from the body, unless an authority has been given for the permanent retention of the tissue. Small samples of tissue retained in the form of tissue blocks or tissue slides are excluded from the disposal requirements.

See **Schedule 1 [14] and [15]**. **Schedule 1 [23]** includes a transitional provision.

Children in the care of the State

It will be an offence for a person to authorise the anatomical examination of a child who was, immediately before his or her death, in the care of the State. See **Schedule 1 [19]**.

Regulation-making powers

The amendments provide for more extensive regulation-making powers.

Regulations may be made with respect to the standards to be complied with in connection with any actions that are authorised under the Act. See **Schedule 1 [21]**.

Schedule 1 [22] and [23] allow savings and transitional regulations to be made.

Miscellaneous

Schedule 1 [3] provides that notes in the Act do not form part of the Act. It also allows a next of kin to delegate his or her functions under the Act to another person. A consequential amendment in **Schedule 1 [1]** makes it clear that a function includes an authority or duty.

Schedule 2 Amendment of Human Tissue Act 1983

Authority to use tissue removed from living person during medical, dental or surgical treatment

The amendments will regulate the use of tissue lawfully removed from the body of a living person during medical, dental or surgical treatment performed in the interests of the health of the person. This includes tissue expelled from the body in the course of such treatment (for example, blood).

As a result of the amendments, the use of such tissue for therapeutic, medical or scientific purposes (other than the purposes of the treatment itself) will be permitted only if the patient or, if the patient has died, a senior available next of kin, has given his or her consent in writing to the use of the tissue for that

purpose. In cases where the patient is a child or is under guardianship, an authority to use the tissue may be given by the senior available next of kin or guardian of the patient.

All tissue must be used in accordance with the relevant consent.

See **Schedule 2 [12], [23], [24] and [27]**. **Schedule 2 [2], [4]–[6] and [15]** are consequential amendments.

Authority to remove and use of tissue from body of deceased person

At present, a designated officer for a hospital may authorise the removal of tissue from the body of a deceased person, and its use for transplantation or for other therapeutic, medical or scientific purposes, if it appears that the deceased person had (during his or her lifetime) consented to that action or it appears that the deceased person had not (during his or her lifetime) expressed an objection to that action and a senior available next of kin has not objected to that action.

Under the amendments, a designated officer will be permitted to give such an authority only if:

(a) the deceased person (during his or her lifetime) consents in writing to the removal and use of the tissue, or

(b) a senior available next of kin consents in writing or in another manner prescribed by the regulations to the removal and use of the tissue.

See **Schedule 2 [13]**.

Authority to conduct post-mortem examination

At present, a designated officer for a hospital may authorise a post-mortem examination of the body of a deceased person if it appears that the deceased person had (during his or her lifetime) consented to a post-mortem examination or it appears that the deceased person had not (during his or her lifetime) expressed an objection to a post-mortem examination and a senior available next of kin has not objected to the post-mortem examination.

Under the amendments, a designated officer will be permitted to give such an authority only if the deceased person (during his or her lifetime), or a senior available next of kin, consents in writing to the post-mortem examination.

The amendments do not affect the power of a coroner to order a post-mortem examination.

See **Schedule 2 [16]**. **Schedule 2 [15]** is a consequential amendment.

Authority to use tissue removed during post-mortem examination

At present, the *Human Tissue Act 1983* provides that tissue removed from the body of a deceased person for the purposes of a post-mortem examination may be used for any therapeutic, medical or scientific purposes.

The amendments provide that tissue may be used for therapeutic, medical or scientific purposes only with the consent in writing of the deceased person (given during his or her lifetime) or a senior available next of kin.

All tissue must be used in accordance with the relevant consent.

See **Schedule 2 [18], [19]** (proposed Division 2 of Part 5) **and [28]**. **Schedule 2 [1], [2], [3], [8], [14] and [17]** include consequential amendments.

Persons who may give authority

The amendments allow a designated officer for a forensic institution (an institution at which post-mortem examinations are carried out) to give authorities under the Act in appropriate circumstances. See **Schedule 2 [1], [2], [3], [8], [16] and [19]**.

Prohibited trading in tissue

The amendments extend the prohibition against entering into a contract or arrangement for the sale or supply of human tissue to the act of offering to enter into such a contract or arrangement. See **Schedule 2 [20]**.

The amendments also exclude from that prohibition tissue that has been subjected to processing or treatment, whether or not the tissue is to be used in

accordance with the directions of a medical practitioner. This makes it clear that, for example, diagnostic kits used by scientists are not subject to the prohibition against sale. See **Schedule 2 [21]**.

Exceptions/exclusions

The amendments make clear that the following things are permitted (without authority under the Act):

(a) the use, for therapeutic, medical or scientific purposes, of small samples of tissue lawfully removed from the body of a person and retained in the form of a tissue slide or tissue block,

(b) the retention of tissue lawfully removed from the body of a person in circumstances prescribed by the regulations, for such period as the regulations authorise, for the purpose of obtaining an authority under the Act to use the tissue for therapeutic, medical or scientific purposes,

(c) anything authorised by or under the *Coroners Act 1980*, the *Anatomy Act 1977* or any other law.

See **Schedule 2 [25] and [29]**.

Conduct of post-mortem examinations

The amendments make it clear that post-mortem examinations are to be conducted having regard to the dignity of the deceased person. See **Schedule 2 [19]** (proposed Division 3 of Part 5).

Enforcement powers

The amendments allow the Director-General of the Department of Health to appoint inspectors for the purposes of enforcing the Act and the regulations. At present, inspectors are appointed under Part 3B of the Act and have powers only in relation to the enforcement of that Part. Inspectors appointed under the new provisions will have enforcement powers in relation to the whole Act. These include the powers currently exercised by inspectors under Part 3B (such as powers of entry and inspection, and powers of seizure) and some new enforcement powers (such as power to require information to be provided or to obtain a search warrant). See **Schedule 2 [22]**.

Schedule 2 [2], [10] and [11] include consequential amendments. **Schedule 2 [32]** includes a transitional provision.

Schedule 3.2 is a consequential amendment to the *Search Warrants Act 1985*.

Children in care of the State

It will be an offence in certain circumstances for a person to consent to or authorise the removal of tissue from the body of a deceased child who was in the care of the State, or the post-mortem examination or use of tissue removed during a post-mortem examination of a deceased child who was in the care of the State. See **Schedule 2 [26]**.

Regulation-making powers

The amendments provide for more extensive regulation-making powers.

Regulations may be made with respect to the making and keeping of records, the provision of information and the standards to be complied with, in connection with any actions that are authorised under the Act. See **Schedule 2 [30] and [31]**.

Schedule 2 [32] allows savings and transitional regulations to be made.

Miscellaneous

Schedule 2 [6] makes it clear that the medical or scientific purposes authorised under the Act include educational purposes associated with medicine or science.

Schedule 2 [9] allows a next of kin to delegate his or her functions under the Act to another person. A consequential amendment in **Schedule 2 [2]** makes it clear that a function includes a power, authority or duty.

Schedule 2 [7] provides that notes in the Act do not form part of the Act.

Schedule 3 Amendment of other Acts

Retention and use of human tissue

The amendments confirm the authority of investigating police and others to remove and use tissue from the body of a deceased person for the purposes of a coroner's investigation, an investigation of an offence or proceedings for an offence, but only where a coroner has ordered a post-mortem examination or other examination or test.

Any such order will also be taken to authorise the retention of small samples of certain tissue and its use in connection with legal and other proceedings.

Accordingly, an authority will not be required in respect of that use under the *Human Tissue Act 1983*.

See **Schedule 3.1 [3]**.

Ordering and conduct of post-mortem examination

The amendments make it clear that a post-mortem examination or other order or test with respect to a deceased person may be ordered by a coroner in order to assist in the investigation of any of the following matters:

- (a) the identity of the deceased person,
- (b) the date and place of death of the deceased person,
- (c) the manner or cause of death of the deceased person.

A senior next of kin will be able to delegate to another person his or her right to object to the post-mortem examination.

The amendments also require all post-mortem examinations or other examinations or tests performed under the *Coroners Act 1980* to be conducted having regard to the dignity of the deceased person.

See **Schedule 3.1 [1], [2] and [4]**.

Search warrants

Schedule 3.4 is a consequential amendment to **Schedule 2 [22]**. It applies the provisions of the *Search Warrants Act 1985* to search warrants obtained under the *Human Tissue Act 1983*.

The *Search Warrants Act 1985* is to be repealed by the *Law Enforcement (Powers and Responsibilities) Act 2002*. **Schedule 3.2 and 3.3** contain provisions that are consequential on that repeal.