

TISSUE TRANSPLANTATION AND THE NATIONAL HEALTH ACT

The National Health Act (NHA) has been introduced to provide a framework for a structured and uniform health system in South Africa.¹

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The National Health Act (NHA) gives effect to the obligations imposed by the Constitution² and other laws affecting national, provincial and local governments regarding health services.

The NHA is divided into 12 chapters. Chapter 8 of the Act deals with the control of blood, blood products, tissues, gametes, postmortem examinations and transplantation. The NHA will replace the Human Tissue Act (HTA)³ once chapter 8 has been brought into effect and the necessary regulations have been promulgated. The provisions in this chapter are largely based on those in the HTA, with some differences and additions, and will be amplified by the regulations.

This article refers to the relevant definitions contained in the NHA, together with the procedures regarding the donation of human tissue and organs from both living and dead persons, but does not include issues such as the use of blood and blood products, gametes or cloning.

DEFINITIONS (S1)

Tissue is defined as 'human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete'. This differs from the definition in the HTA because it now includes 'skin' but omits the HTA provision about 'any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person' (e.g. a pacemaker).

Organ is defined for the first time as 'any part of the body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete'. Although organ is separately defined it is also included in the definition of tissue.

Tissue is defined as 'human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete'.

A person over the age of 16 years may donate his or her body or tissue in a will, or in a document signed by him or her and two competent witnesses (persons older than 14 years), or in an oral statement made in the presence of two competent witnesses.

For the first time **death** is defined as 'brain death'. This definition has been implicitly used by the courts but has never been specifically defined by them as a criterion of death.⁴

An **authorised institution** refers to any institution designated by the minister as such. It may acquire, use, or supply human tissue from the body of a living or deceased person for certain approved purposes, including therapeutic purposes such as transplantation into living persons.

A **user** is defined as 'a person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service'. If the person receiving treatment or using a health service is below the age of consent for medical treatment and operations,⁵ the term user includes the person's parent or guardian or another person authorised by law to act on their behalf (e.g. spouse or partner). This would apply to patients receiving or donating tissues or organs.

ALLOCATION AND USE OF HUMAN ORGANS

As a result of the recent allegations regarding organ transplants between foreign nationals in South Africa, the

allocation and use of human organs will be strictly controlled.⁶

An organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the country without the minister's written authorisation. The minister has yet to prescribe the criteria for the approval of transplant facilities and the measures to be followed. Human organs obtained from deceased persons for the purpose of transplantation may be used only in the prescribed manner. A person who charges a fee for a human organ is guilty of an offence and, on conviction, is subject to a fine or imprisonment of up to 5 years, or both (s. 61).

TISSUE DONATIONS BY LIVING PERSONS

A person may not remove tissue from a living person for transplantation except in a hospital or an authorised institution, and then only on the written authority of the medical practitioner in charge of clinical services in such hospital or institution, or any other medical practitioner authorised by him or her (s. 58). The medical practitioner who gives authorisation may not participate in a transplant that he or she has authorised (s. 58). Only a registered medical practitioner or dentist may remove from, use, or transplant tissue into another living person (s. 59).

The Act makes it an offence for a person who has donated tissue to receive financial or other reward for such donation, except for the reimbursement of the reasonable costs incurred by such a person (e.g. travel costs, medical bills). It is also an offence to sell or trade in human tissue. A person convicted of either offence may be subject to a fine or imprisonment for up to 5 years, or both (s. 60).

Revocation of donation

A donor may, before transplantation of the relevant organ into the donee, revoke the donation in the same way in which it was made. In the case of donation by a will or other document, revocation may be by the intentional destruction of such will or document (s. 65).

Donation of human bodies and tissue of deceased persons

A person over the age of 16 years may donate his or her body or tissue in a will, or in a document signed by him or her and two competent witnesses (persons older than 14 years), or in an oral statement made in the presence of two competent witnesses. The will, document or statement should indicate the institution or person intended as donee, and should specify how the tissue should be used after death. Failure to nominate a specified donee will render the donation null and void (s. 62).

Where a donation of tissue has not been made or where the deceased has not prohibited a donation while alive, certain relatives may consent to a donation. The NHA provides for a specific order of precedence in this regard, namely the spouse, partner, major child, parent, guardian, major brother or major sister of that person. The list of persons authorised to give consent has been expanded beyond the HTA to include partners. Where such persons cannot be located after the death of the deceased, the Director-General (of Health) may donate any specific tissue of that person to an institution or a person — provided all the prescribed steps have been taken to locate the person authorised to give consent (s. 66). The prescribed steps have not yet been promulgated and care needs to be taken to ensure that this provision is not abused. The wording in the HTA is 'reasonable steps' (s. 2) and it may be that the courts, when interpreting the term 'prescribed steps', may also introduce the requirement of reasonableness.

MINISTER'S POWER TO MAKE REGULATIONS (S. 68)

The minister may make regulations regarding the following:

- removal of donated tissue or cells from persons or from postmortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons
- tissue transplantation
- supply of tissue or organs
- importation and exportation of tissue
- records and registers to be kept by persons and institutions
- returns and reports, including extracts from registers to be submitted to specified persons and institutions
- acquisition, storage, harvesting, utilisation, or manipulation of tissue for any purpose
- any other matter relating to regulating the control and the use of human bodies, tissue, organs, etc.

In addition, the minister, with the approval of the cabinet minister

responsible for finance, may make regulations concerning the payment of persons or institutions regarding the procurement, storage, supply, import or export of human bodies, tissue, etc.

MEASURES NOT PROVIDED FOR IN THE NHA THAT EXIST IN THE HTA

The HTA provides that, in the case of organ transplantation, the death of the deceased has to be determined by two doctors, one of whom has to have been qualified for least 5 years and neither of whom may be members of the transplant team (s. 7). It is envisaged that this provision will be incorporated in the regulations of the NHA.

In terms of the HTA, if a body has been donated to an institution, the tissue must be harvested within a period of 24 hours, whereafter the body may be claimed by the relatives for cremation or burial (s. 7).

This provision may also be included in the regulations of the NHA.

In the HTA, if a deceased person has not donated his or her body or forbidden a donation, certain categories of tissue or organs may be removed without consent or official authorisation. These include the pituitary gland, bone, tendon, cartilage, skin, heart valves, eyes, bone, dura mater, liver, aorta and heart auricle (s. 14). Presumably this section has been omitted in the NHA because it would conflict with other provisions in this Act and the Constitution regarding consent. The HTA specifically provides that organ donations should be kept confidential and there should be no publicity about the identity of the donor or the donee. Although this provision is not included in the NHA, it is covered by the general ethical rules of the profession, as well as by the common law and the Constitution.

References available on request.

IN A NUTSHELL

The NHA provisions regarding tissue and organ donation are generally similar to those in the HTA.

The NHA, however, for the first time introduces definitions of death and organ.

The NHA also provides strict controls for the transplantation of organs into non-South African citizens or non-permanent residents, and outlaws the charging of fees for human organs.

It also expands the list of persons who can give consent to donations from deceased persons to include partners.

Matters not covered by the NHA include the determination of death for the removal of organs for transplantation by doctors, the harvesting of tissue within 24 hours from donated bodies, the favourable removal of certain tissues (e.g. eye tissue), and the question of confidentiality and publicity regarding organ transplants. Some of these issues may be covered in the regulations yet to be published.