

APPENDIX E: NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003) (CHAPTER 8: SECTION 53-68)

CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS

Establishment of national blood transfusion service

- 53.** (1) The Minister must establish a blood transfusion service for the Republic by granting a licence to a non-profit organisation, which is able to provide a blood transfusion service throughout the territory of the Republic.
- (2) The holder of the licence granted in terms of subsection (1)-
- (a) must comply with prescribed norms and standards and must provide the prescribed blood transfusion and related services.
 - (b) may establish regional units, for the delivery of blood transfusion services, which must function under the control of the licence holder: and
 - (c) has the sole right to provide a blood transfusion service in the Republic.
- (3) Any person other than the holder of the licence granted in terms of subsection (1) who provides a blood transfusion service in the Republic, is guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

Designation of authorised institution

- 54.** (1) The Minister may, by notice in the *Gazette*, designate any institution other than an institution contemplated in section 63 as an authorised institution.
- (2) An authorised institution may-
- (a) acquire, use or supply the body of a deceased person for any of the purposes referred to in section 64:
 - (b) acquire or use any tissue lawfully imported or removed from the body of living or deceased person for any of the purposes referred to in section 56 or 64, as the case may be:
 - (c) supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in section 58 or 64: and
 - (d) acquire, use and supply blood products for any of the purposes referred to in section 56 or 64.
- (3) The Minister may, in the notice contemplated in subsection (1), impose conditions in respect of the exercise of a power referred to in subsection (2).

Removal of tissue, blood, blood products or gametes from living persons

- 55.** A person may not remove tissue, blood, a blood product or gametes from the body of another living person for the purpose referred to in section 56 unless it is done-
- (a) with the written consent of the person from whom the tissue, blood, blood products or gametes are removed granted in the prescribed manner: and
 - (b) in accordance with prescribed conditions.

Use of tissue, blood, blood products or gametes removed or withdrawn from living persons

56. (1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed.
- (2) (a) Subject to paragraph , the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):
- (i) tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act No. 17 of 2002);
 - (ii) tissue which is not replaceable by natural processes from a person younger than 18 years;
 - (iii) a gamete from a person younger than 18 years; or
 - (iv) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells,
- (b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition, which may be necessary in respect of such removal or withdrawal.

Prohibition of reproductive cloning of human beings

57. (1) A person may not-
- (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or
 - (b) engage in any activity, including nuclear transfer or embryo splitting, for the purpose of the reproductive cloning of a human being.
- (2) The Minister may, under such conditions as may be prescribed, permit therapeutic cloning utilising adult or umbilical cord stem cells.
- (3) No person may import or export human zygotes or embryos without the prior written approval of the Minister.
- (4) The Minister may permit research on stem cells and zygotes, which are not more than 14 days old on a written application and if-
- (a) the applicant undertakes to document the research for record purposes; and
 - (b) prior consent is obtained from the donor of such stem cells or zygotes.
- (5) Any person who contravenes a provision of this section or who fails to comply therewith is guilty of an offence and is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.
- (6) For the purpose of this section-
- (a) “reproductive cloning of a human being” means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose; and
 - (b) “therapeutic cloning” means the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

Removal and transplantation of human tissue in hospital or authorised institution

58. (1) A person may not remove tissue from living person for transplantation in another living person or carry out transplantation of such tissue except-
- (a) in a hospital or an authorised institution; and
 - (b) on the written authority of-
 - (i) the medical practitioner in charge of clinical services in that hospital or authorized institution, or any other medical practitioner authorised by him or her; or

- (ii) in the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner authorised thereto by the person in charge of the hospital or authorised institution.
- (2) The medical practitioner contemplated in subsection (1) (b) may not participate in a transplant for which he or she has granted authorisation in terms of that subsection

Removal, use or transplantation of tissue, and administering of blood and blood products by medical practitioner or dentist

59. (1) For the purpose of this Chapter, only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes contemplated in section 56 or transplant tissue so removed into another living person.
- (2) Subject to Medicine and Related Substances Control Act, 1965 (Act No. 101 of 1965), only a registered medical practitioner or dentist, or a person acting under the supervision or on the instructions of a medical practitioner or dentist, may for the purposes of this Chapter administer blood or a blood product to, or prescribe blood or a blood product for, a living person.

Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes

60. (1) No person, except-
- (a) a hospital or an institution contemplated in section 58(1)(a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in section 56 or 64.
 - (b) A person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or blood products.
- (2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.
- (3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her.
- (4) It is an offence for a person-
- (a) who has donated tissue, gamete, blood or blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and
 - (b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.
- (5) Any person convicted of an offence in terms of subsection (4) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment

Allocation and use of human organs

61. (1) Human organs obtained from deceased persons for the purpose of transplantation or treatment or medical or dental training or research, may only be used in the prescribed manner.

- (2) Human organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures.
- (3) An organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing.
- (4) The Minister must prescribe-
 - (a) criteria for the approval of organ transplant facilities; and
 - (b) procedural measures to be applied for such approval.
- (5)(a) A person who contravenes a provision of this section or fails to comply therewith or who charges a fee for a human organ is guilty of an offence.
 - (c) Any person convicted of an offence in terms of paragraph (a) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.

Donation of human bodies and tissue of deceased persons

- 62.** (1) (a) A person who is competent to make a will may-
- (i) in the will
 - (ii) in a document signed by him or her and at least two competent witnesses; or
 - (iii) in an oral statement made in the presence of at least two competent witnesses, donates his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Act.
- (b) A person who makes a donation as contemplated in paragraph (a) must nominate an institution or a person contemplated in section 63 as donee.
- (c) If no donee is nominated in terms of paragraph (b), the donation is null and void.
- (d) Paragraph (b) does not apply in respect of an organ donated for the purposes contemplated in section 61 (1) and the donee of such organ must be determined in terms of section 61 (2).
- (2) In the absence of a donation under subsection (1) (a) or of a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may after that person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63.
- (3) (a) The Director-General may, after the death of a person and if none of the persons contemplated in subsection (2) can be located, donate any specific tissue of that person to an institution or a person contemplated in subsection (2).

Human bodies, tissue, blood, blood products or gametes may be donated to prescribed institution or person

- 63.** A human body, tissue, blood, blood products or gametes may be donated by any person contemplated in section 55(a) or 62 to any prescribed institution or person for any purpose contemplated in section 56 or 64 (1)

Purposes of donation of body, tissue, blood or blood products of deceased persons

- 64.** (1) A donation in terms of section 62 may only be made for-
- (a) the purposes of the training of students in health sciences;
 - (b) the purposes of research;
 - (c) the purposes of the advancement of health sciences;
 - (d) therapeutic purposes, including the use of tissue in any living person; or
 - (e) the production of a therapeutic, diagnostic or prophylactic substance.

- (2) This Act does not apply to the preparation of the body of a deceased person for the purposes of embalming it, whether or not such preparation involves the-
- (a) making of incisions in the body for the withdrawal of blood and the replacement thereof by a preservative; or
 - (b) restoration of any disfigurement or mutilation of the body before its burial.

Revocation of donation

65. A donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document.

Post-mortem examination of bodies

66. (1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if-
- (a) the person, while alive, gave consent thereto;
 - (b) the spouse, partner, major child, parent, guardian, major brother or major sister of the deceased, in the specific order mentioned, gave consent thereto;
 - (c) or such an examination is necessary for determining the cause of death
- (2) A post mortem examination may not take place unless-
- (a) the medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner, has authorised the post mortem examination in writing and in the prescribed manner; or
 - (b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, has authorised the post mortem examination in writing and in the prescribed manner.

Removal of tissue at post-mortem examinations and obtaining of tissue by institution and persons

67. (1) (a) The Minister may, on the written application of an institution or person requiring tissue for a purpose contemplated in section 64(1), authorise that institution or person, in writing, to obtain such tissue from a medical practitioner contemplated in subsection (3) or a person or an institution contemplated in section 63.
- (b) The Minister may impose any condition on the institution or person to which or to whom he or she has granted an authorisation in terms of paragraph (a)
- (c) This Act does not prevent persons or institutions from acquiring tissue in terms of the National Heritage Resources Act, 1999 (Act No.25 of 1999), for the purposes of that Act.
- (2) The medical practitioner in charge of clinical services in the hospital or authorised institution or of the mortuary in question, or any other medical practitioner authorised by such practitioner, or, in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorised by the person in charge of such hospital or authorised institution, may, in writing and in the prescribed manner, authorise-
- (a) a prescribed institution or person contemplated in section 63; or
 - (b) an authorised institution making application thereof in writing, to remove any specified tissue from the body concerned before burial thereof.
- (3) Despite anything to the contrary in any other law, a medical practitioner who conducts a post-mortem examination in terms of-
- (a) section 3 of the Inquests Act, 1959 (Act No.58 of 1959); or
 - (b) section 71 (1)(a) or (b),
- must remove or cause to be removed from a body such tissue as may be specified in an authorisation under subsection (1) and must hand it over to the institution or person in possession of the authorisation.

- (4) The removal contemplated in subsection (3) may not be effected if-
- (a) the removal of the tissue is likely to affect the outcome of the examination; or
 - (b) the body or tissue in question has been donated or if the removal would be contrary to a direction given by the deceased before his or her death.

Regulations relating to tissue, cells, organs, blood, blood products and gametes

68. (1) The Minister may make regulations regarding-
- (a) the post-mortem examination of bodies of deceased persons
 - (b) the preservation, use and disposal of bodies, including unclaimed bodies;
 - (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post-mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons;
 - (d) tissue transplants;
 - (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue;
 - (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
 - (g) the importation and exportation of tissue, human cells, blood, blood products or gametes
 - (h) the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood;
 - the administering of blood and any blood product to living persons;
 - (i) the production, packaging, sealing, labelling and supplying of blood and blood products;
 - (j) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;
 - (k) the artificial fertilisation of persons;
 - (l) the appointment and functions of inspectors of anatomy and investigating officers;
 - (m) the records and registers to be kept by persons and institutions;
 - (n) the returns and reports, including extracts from registers, to be submitted to specified persons and institutions;
 - (o) the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose;
 - (p) the appointment and functions of inspectors of the national blood transfusion service and progenitor cell transplant institutions; and
 - (q) any other matter relating to regulating the control and the use of human bodies, tissue, organs, gametes, blood and blood products in humans.
- (2) The Minister, with the concurrence of the Cabinet member responsible for finance, may make regulations concerning the payment of persons or institutions in connection with procurement, storage, supply, import or export of human bodies, tissue, blood, blood products or gametes.
- (3) The Minister may, if it is consistent with the objects of this Act and upon such conditions as the Minister may deem fit, by notice in the *Gazette* exempt a person or category of persons from any or all of the regulations made under this section.