

Human tissue legislation in South Africa: Focus on stem cell research and therapy

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The South African (SA) legislative framework follows a hierarchical structure aligned with the relevant level of government (national, provincial or local) responsible for applying and monitoring the legislation, with the overarching and progressive Constitution as the supreme law. Delegated legislation (also known as secondary or subordinate legislation, e.g. regulations) 'adds flesh' to Acts of Parliament, or other forms of original legislation. The control and use of human tissue in South Africa is primarily governed by the National Health Act and relevant regulations, although other national acts, in differing degrees, are also relevant to this complex field. These include, among others, the Medicines and Related Substances Act, the Consumer Protection Act, the Children's Act and the Inquest Act. Regulations generally only require ministerial and not parliamentary approval and are therefore (theoretically) easier to amend. In principle, the drafting of Acts should be preceded by policy documents, which contain broad foundational guidelines or a statement of intent in the area in question. Another useful source in the interpretation of legislation, albeit not officially recognised as legislation, is guidelines (sometimes referred to as standards), that may provide greater granularity than the regulations. Although neither policy documents nor guidelines are directly legally binding, a lack of compliance with the latter may have legal significance. In this article, the components of the hierarchical structure relevant to the legal regulation of human tissue in SA will be examined, with a specific focus on stem cell research and therapy. A critical analysis of the accuracy, relevance, redundancy and completeness (or lack thereof) of these components will be provided. Furthermore, recommendations outlining the procedures that should be undertaken to remedy the inadequacies of the current legislative framework will be suggested. Given the well-defined structure of this framework and the relative youth of human tissue legislation in SA, the legislator has an opportunity to mirror the values and principles embodied in the Constitution by addressing these inconsistencies, and in the process develop a globally-applicable and appropriate legislative model in the fields of stem cell research and therapy.

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Human tissue legislation is complex. It is characterised by an ever-changing landscape in which advances in science and medicine need to be accommodated.

A high degree of technical expertise is required to ensure that the legislation is accurate, appropriate and unambiguous. However, it is generally accepted that the law has struggled to keep pace with advances in science and technology.^[1]

The legislative framework governing the control and use of human tissue has at its apex the Constitution of the Republic of South Africa, 1996, relevant statutes and regulations, as well as standards and guidelines. The legal force and status of each of these and the

extent to which they have been developed in South Africa (SA) with regard to the regulation of human tissue are summarised in Table 1. The development of legislation is preceded by a policy document detailing the objectives and expectations of the proposed legislation.

Stem cell research and therapy

Stem cells are defined as undifferentiated cells capable of self-renewal that can differentiate into specialised cell types in response to appropriate environmental (e.g. chemical, mechanical) cues. There are several types of stem cells, which for the purpose of this discussion we will divide into pluripotent and adult. Pluripotent stem cells include embryonic stem (ES) cells and induced pluripotent stem (iPS) cells, while adult stem cells include haematopoietic and mesenchymal stem cells (HSCs and MSCs). Most other stem cell types can be included in this broad definition. Pepper, Gouveia and Slabbert will deal with pluripotent stem cells in detail in the article on pg. 23 of this special issue. A limited number of clinical trials involving pluripotent stem cells are underway, in which differentiated and specialised derivatives of these cells are being assessed.

With regard to adult stem cells, HSC transplantation is the only universally accepted and routinely applied form of stem cell therapy. The potential for stem cells to be used in the treatment of a much broader spectrum of diseases is real, but hard to measure. This includes epidermal cells for skin defects and autologous cartilage

Table 1. The legislative framework governing the control and use of human tissue

Level	Legally-binding	Human tissues
Constitution	Yes	
Policy	No	Limited
Act	Yes	Yes
Regulations	Yes	Incomplete
Guidelines standards	No	None officially

implantation for articular cartilage defects. Clinical trials are underway to assess the use of stem cells in the treatment of heart disease. Likewise, preclinical and early clinical trials have highlighted the potential of stem cells for the treatment of diabetes, spinal cord injury and other central nervous system disorders (e.g. cerebral palsy and Parkinson's disease). Adult stem cells *per se* display very few complications, while the major potential risk associated with pluripotent cells is tumorigenicity.

There are several essential pillars to a successful cell therapy environment. These include a robust regulatory environment, quality assurance and accreditation. Also essential is an appropriate informed consent process, in which the benefits and potential side-effects of the therapy are clearly laid out. The legal requirements for tissue donation should also be clearly articulated to curtail possible trade and trafficking in human tissue.

What is the current situation in SA? Hematopoietic stem cell transplantation has been practised successfully in the country for several decades. Sources of stem cells mainly include bone marrow and peripheral blood, which may be autologous, or allogeneic. Umbilical cord-blood-derived stem cells have also been used. SA also has a Bone Marrow Registry (SABMR)^[2] that sources stem cells from unrelated voluntary donors for allogeneic transplantation. SA does not at present have a public cord-blood stem cell bank. In SA private cord-blood banking is offered by Netcells Biosciences and Cryo-Save South Africa. The difference between public and private banks is essentially the difference between an anonymous donation versus storage for private use: in the case of a public bank, cord blood is donated altruistically and is available for any histocompatible patient who needs an allogeneic transplant, while in the case of a private bank, the bank is paid to store cord-blood stem cells for autologous use or for use by next-of-kin. Private banks are contractually obliged to return the stored cells on request and at the bank's expense, exclusively to the owner (or a contractually determined beneficiary).

Human tissue legislation – objectives

Human tissue legislation broadly aims to protect the individual from harmful and unethical practices, while at the same time giving effect to the individual's right to autonomy and self-determination as this relates to decisions regarding the use of his or her own stem cells. The Constitution directs in section 39(2) that, when interpreting legislation, every court, tribunal or forum 'must promote the spirit, purport or objects of the Bill of Rights', which in essence refers to the promotion of the public interest. The legislative process should strive to further the goals and objectives of the Constitution, which includes the promotion of human rights. For example, all South Africans should be able to share in the benefits arising from advances in medical science in an equitable and sustainable manner.

In developing legislation, objectives should be realistic and every effort should be made to ensure simplicity and clarity. In the context of the regulation of human tissue, legislation should be enabling and not be unduly restrictive so as to avoid stifling basic and clinical research and biotechnological innovation. If legislation includes sanctions, these should be unambiguous and legally justified. Those affected by any legislative restriction or penalty should be aware of the limitations and the consequences of any transgressions.

In order to achieve all of the above, South African-specific objectives need to be combined with international best practice and the involvement of local professional societies needs to be encouraged.

The South African Constitution

The Constitution of the Republic of South Africa, 1996, enshrines the values on which SA's constitutional democracy is founded. Chapter 2 of the Constitution (the Bill of Rights) contains the fundamental rights and freedoms. These rights may be limited by section 36 of the Constitution and are therefore not absolute. However, some of the rights that are specifically relevant in the context of the regulation of human tissue are the right to equality (section 9); the right to human dignity (section 10); the right to life (section 11); the right to privacy (section 14); the right of a person to freedom and security, which includes the right to security in and control over one's body and the right not to be subjected to medical or scientific experiments without informed consent (section 12); and the right of access to healthcare (section 27).

The following four principles, espoused by Beauchamp and Childress^[3] provide a very useful framework for the consideration of medical ethics issues generally, namely:

- **Autonomy**, which includes respecting the patient's right to make decisions regarding her or his treatment. In this respect, consent always needs to be informed in the broadest sense with the patient being made aware of both the benefits and possible side-effects. The importance of an adequate Materials Transfer Agreement cannot be overemphasised, particularly in a country in which discrimination and benefit sharing have not been adequately addressed. Both autonomy and self-determination are recognised in the provisions regarding the right to bodily and psychological integrity, the right to privacy and the right to life. Human dignity, inextricably linked to health and life as a constitutional value, informs the interpretation of all other rights.^[4]
- **Beneficence**, the moral foundation on which the medical profession rests, includes a consideration of the benefits of treatment against risks and costs. It is also critical that the therapy being applied has previously been shown to be of benefit in patients with a similar condition, preferably through the avenue of well-controlled and appropriately designed clinical trials. Beneficence finds expression in the provisions of the Constitution that relate to the right to life and the right of access to healthcare services (within the limits of available resources).
- **Non-maleficence**, which implies avoiding the causation of harm. The harm should not be disproportionate to the benefits of the treatment. Early phase clinical trials (phases I and II) are required to establish the facts. This principle is expressed, for example, in the constitutional right not to be subjected to medical or scientific experiments without informed consent.
- **Justice and fairness**, which require that benefits, risks and costs be distributed fairly. In the SA context, distributive justice will ensure that all South Africans will benefit from cell-based therapy. The right to equality and the right of access to healthcare services embody these principles.

These four principles are not only aligned with the Constitution, but if observed, will promote the realisation of the rights articulated therein, in addition to assisting in deterring possible criminal and unprofessional conduct in the context of stem cell research and therapy.

The Acts

Principally Chapter 8 of the National Health Act (NHA) 61 of 2003 governs the legal regulation of human tissues. The NHA has

repealed and replaced the Human Tissue Act 65 of 1983, which governed many areas of human tissue legislation but was clearly lacking with regard to more recent developments in the field. Briefly, the National Health Act makes provision in Chapter 8 for control of the use of blood, blood products, tissue and gametes in humans. This includes provisions regulating, among others, the removal and use of tissue, blood, blood products or gametes from living persons and the transplantation of tissue from one living person to another. The Act also regulates payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes, as well as the donation of human bodies and tissue from deceased persons. Chapter 8 furthermore provides for the allocation and use of human organs, as well as the purposes of the donation of the body, tissue, blood or blood products of deceased persons. The post-mortem examination of bodies, including the removal of tissue at post-mortem examinations and obtaining of tissue by institutions and persons are also regulated by the Act. In addition, not only is trade or trafficking in the human body or body parts prohibited in terms of section 60(4), as is the exploitation of the body as a commodity, but such conduct would also violate the right to human dignity reflected in the Constitution. The Medicines and Related Substances Control Act 101 of 1965 (Medicines Act) is more relevant to the clinical translation of stem cell therapy than the research component of stem cells, while the Children's Act 38 of 2005, the Inquest Act 58 of 1959 and the Consumer Protection Act 68 of 2008 all have bearing on stem cell research and therapy in SA.

The NHA was assented to by the President on 18 July 2004 and came into force on 2 May 2005. However, the main section dealing with human tissues, namely Chapter 8 entitled the 'Control of use of blood, blood products, tissue and gametes in humans', was only fully enacted as recently as 2 March 2012. As mentioned previously, matters pertaining to human tissues were previously legislated under the Human Tissue Act 65 of 1983, which was repealed with the enactment of the final sections of the NHA in 2012.^[5]

Chapter 8 of the NHA covers seven areas that are relevant to human tissues. These include:

- Blood and blood products
- Assisted reproductive technology
- Cell-based therapy
- Transplantation
- DNA and genetic services
- Tissue banks
- Examination, allocation and disposal of human bodies and tissues.

'Tissue' is defined in section 1 of the NHA as 'human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete'. An organ is defined in the same section as 'any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories'. Suggested alternatives to these definitions are provided in Table 2.

With regard to human cloning, the manipulation of any genetic material for the purpose of reproductive cloning of a human being is prohibited in terms of section 57(1) of the NHA, read together with section 57(6)(a). Cloning for therapeutic purposes is provided for in section 57(2) of the Act, read together with section 57(6)(b).

These definitions (i.e. 'reproductive cloning of a human being' and 'therapeutic cloning') are however problematic; alternatives are provided in Table 3. A person contravening or failing to comply with this section is guilty of an offence and is liable, on conviction, to a fine or to imprisonment for a period not exceeding 5 years or to both a fine and such imprisonment (section 57(5)).

Research on stem cells and zygotes which are not more than 14 days old may in terms of section 57(4) of the NHA only be conducted with the permission of the Minister and under certain conditions, namely that the research shall be documented and prior consent be obtained from the donor of such stem cells or zygotes.

Section 56 of the NHA ('Use of tissue, blood, blood products or gametes removed or withdrawn from living persons') provides that that the removal or withdrawal of stem cells (excluding umbilical cord progenitor cells) from a living person for medical or dental purposes requires ministerial authorisation. Specific restrictions regarding the removal of tissue, blood, blood products or gametes from living persons are found in section 56(2), which states as follows:

'(2) (a) Subject to paragraph (b), 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.'

This implies that HSC transplantation, which has been practised for several decades in SA, requires ministerial authorisation, as will all future applications of stem cell therapy requiring removal or withdrawal of stem cells from a living person. The exception appears to be umbilical cord progenitor cells, which implies that other cells harvested from cord blood (i.e. earlier primitive stem cells that are not progenitors and non-haematopoietic stem cells) will also require ministerial authorisation. The legislator's reason for making this distinction is not apparent. On the other hand, no mention is made of the requirement for ministerial approval in the Regulations Relating to the Use of Human Biological Material, which provide that biological material – which includes progenitor stem cells^[6] – may be removed or withdrawn from living adult persons with their informed consent.^[7] It is suggested that section 56(2)(a)(iv) above be changed to refer only to 'embryonic or fetal tissue'.

In addition to Chapter 8, several important areas are covered by Chapter 9 of the NHA which deals with 'National Health Research and Information'. Section 71, for example, entitled 'Research on or experimentation with human subjects', states that all research conducted on minors (e.g. persons younger than 18 years) for non-therapeutic purposes requires ministerial authorisation (section 71(3)), whereas in the instance of research for therapeutic purposes, ministerial authorisation is apparently not required

Table 2. Definitions from the National Health Act and Regulations thereto relating to tissues and organs

Name	Definition	Source	Comment / proposal
tissue	human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete	National Health Act (No. 61 of 2003)	Proposal – replace with: human tissue, and includes skin and appendages, flesh, bone, bone marrow, body fluid, a gland, an organ, but excludes blood, gametes and stem cells
	a functional group of cells. The term is used collectively in Regulations to indicate both cells and tissue	Regulations Relating to Tissue Banks (No. R. 182)	
organ	any part of the human 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	National Health Act (No. 61 of 2003)	Proposal – replace with: any part of the human 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, a gamete or stem cells
biological material	material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells, small tissue biopsies and growth factors from the same	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
biological samples	no definition in the current legislation		Proposal: samples derived from tissue and blood including cells, DNA, RNA and protein
body specimen	any body sample which can be tested to determine the presence or absence of HIV infection	Regulations regarding the Rendering of Clinical Forensic Medicine Services (No. R. 176)	
body fluid	any body substance which may contain HIV or any other sexually transmissible infection, but does not include saliva, tears or perspiration	Regulations regarding the Rendering of Clinical Forensic Medicine Services (No. R. 176)	
substance	tissue, blood, blood product or gamete	Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes. (No. R. 181)	
to traffic	no definition in the current legislation		Proposal: to recruit, transport, transfer, harbour or receive tissue by means of threat, coercion, abduction, fraud, deception or the abuse of power of a position of vulnerability, or to give or receive payments or benefits to achieve the transfer of tissue

(section 71(2)), but only the consent of the parent or guardian, or the relevant child if he or she is capable of understanding. The rationale behind the requirement for ministerial authorisation where research or experimentation is to be conducted on a minor for non-therapeutic purposes (not benefiting the specific minor), but not for therapeutic purposes, is unclear. The Minister may not authorise such research for non-therapeutic purposes involving a minor if, among others, the research poses a 'significant risk' to the

health of the minor, or 'some risk', though there is the likelihood of 'some benefit' to the minor (section 71(3)(b)). Paradoxically, it would seem that ministerial authorisation for the latter would be important. The purpose of this is clearly to protect minors from unscrupulous research practices, but in the absence of a definition of what 'significant risk' or 'some risk' are, which differ from the requirements stated in the national ethics guidelines,^[9] this adds more confusion.^[9]

Table 3. Definitions from the National Health Act and Regulations thereto relating to stem cells

Name	Definition	Source	Comment /proposal
cell	the basic structural and functional unit in people and all living things and is a small container of chemical and water wrapped in a membrane	Regulations Relating to the Artificial Fertilisation of Persons (No. R. 175)	This definition is not appropriate
	the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
cultured cells	cells that have been grown outside the body	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
	any human cells grown in vitro supported by suitable growth media	Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes (No. R. 181)	
stem cell	a cell that has both the capacity to self-renew as well as to differentiate into mature, specialised cells	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
	a cell that has both the capacity to self-renew as well as to differentiate into mature, specialised cells	Regulations Relating to Blood and Blood Products (No. R. 179)	
	any embryonic stem cell or circulating, bone marrow, umbilical cord or haemopoietic progenitor cell, or any cell that is capable of replicating or proliferating and giving rise to a differentiated cell	Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes (No. R. 181)	
	cells that have both the capacity to self-regenerate as well as to differentiate into mature specialised cells	Regulations Relating to Stem Cell Banks (No. R. 183)	
progenitor cells	stem cells which give rise to a distinct stem cell line	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
umbilical cord blood stem cell	stem cells found in umbilical cord blood	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
embryonic stem cell	any cell from the 30-200 inner cell mass of the blastocyst	Regulations Relating to the Use of Human Biological Material (No. R. 177)	
transgenic cells	cells derived from a species other than human	Regulations Relating to the Use of Human Biological Material (No. R. 177)	Definition incorrect Proposal: <i>xenogeneic</i> to replace "transgenic"
reproductive cloning of a human being	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	National Health Act (No. 61 of 2003) Section 57(6)(a)	Proposal – replace with: <i>the manipulation of cells, gametes, zygotes or embryos or genetic material derived therefrom in order to achieve the reproduction of a human being, and includes but is not limited to nuclear transfer and embryo splitting</i>

Continued ...

Table 3. (continued) Definitions from the National Health Act and Regulations thereto relating to stem cells

Name	Definition	Source	Comment /proposal
therapeutic cloning	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	National Health Act (No. 61 of 2003) Section 57(6)(b)	Definition should include somatic cell nuclear transfer – for example, replace with: <i>use of embryonic stem cells, which are derived from a blastocyst following somatic cell nuclear transfer, for therapeutic purposes</i>

Table 4 Regulations published in Government Gazette No. 35099 on 2 March 2012

Regulation No.	Title	Pages
No. R. 175	Regulations Relating to Artificial Fertilisation of Persons	GG 35099 pages 3-21
No. R. 176	Regulations Regarding the Rendering of Clinical Forensic Medicine Services	GG 35099 pages 22-30
No. R. 177	Regulations Relating to the Use of Human Biological Material	GG 35099 pages 31-38
No. R. 179	Regulations Relating to Blood and Blood Products	GG 35099 pages 62-74
No. R. 180	Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes	GG 35099 pages 75-96
No. R. 181	Regulations Relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes.	GG 35099 pages 97-124
No. R. 182	Regulations Relating to Tissue Banks	GG 35099 pages 125-141
No. R. 183	Regulations Relating to Stem Cell Banks	GG 35099 pages 142-158

Regulations

Various sets of regulations relating to Chapter 8 of the NHA came into effect on 2 March 2012 (Table 4). These include regulations relating to the general control of human bodies, tissue, blood, blood products and gametes;^[10] the use of human biological material;^[11] blood and blood products;^[12] import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, fetal tissue, zygotes and gametes;^[13] stem cell banks^[14] and tissue banks.^[15] With regard to some of these sets of regulations that relate to human tissue, there is a degree of redundancy and overlap. Definitions, for example, are not harmonised, both between different regulations and relative to the NHA. In addition, there are at present no regulations regarding cell-based therapy, bio-banks or transplantation.

With regard to definitions, a cell is defined in Regulations Relating to the Artificial Fertilisation of Persons as ‘the basic structural and functional unit in people and all living things and is a small container of chemical and water wrapped in a membrane’ (Table 3). This definition is clearly wanting for detail, which is necessary in the modern setting of highly sophisticated technology. On the other hand, the regulations on the use of human biological material defines a cell as ‘the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things’, which is more appropriate.

Transgenic cells are defined in the Regulations Relating to the Use of Human Biological Material as cells being ‘derived from a species other than human’. The universally accepted definition of cells derived from a species other than human is ‘xenogeneic’. For example,

one source^[16] defines xenogeneic as ‘derived or obtained from an organism of a different species, as a tissue graft’.

Transgenic on the other hand means an organism whose genome has been altered by the transfer of a gene or genes through recombinant DNA techniques from another species or breed using recombinant DNA techniques, e.g. transgenic mice.^[17] It is understood that the foreign genes are in the transgenic animal’s germ-cell DNA and so can be transmitted from one generation to the next.^[18]

Clearly this and other frankly incorrect definitions require urgent amendment.

Guidelines and standards

With regard to guidelines and standards, none have been officially published or endorsed by the National Department of Health in the human tissue field. As a result and in response to the need to provide clarity to professionals working in these fields, several professional bodies have established their own guidelines. These bodies are listed in Table 5.

It should be noted, however, that national standards for cellular therapy product collection, processing, storage and distribution have been drafted and will hopefully be published in the near future. These standards do not include stem cell therapy *per se*, which would for now need to be covered in SA by the South African Stem Cell Transplantation Society standards. It is important that the drafting of all guidelines and standards be done in close alignment with national professional bodies, as well as international bodies such as the Foundation for the Accreditation of Cellular Therapy,^[19] the Joint

Table 5. Professional Bodies: Human tissues

Area	Professional body	Guidelines
Transplantation	Southern African Transplantation Society (SATS)	Yes http://www.sats.org.za/Guidelines.asp
Assisted reproductive technology	Southern African Society of Reproductive Medicine and Gynaecological Endoscopy (SASREG)	Yes http://www.fertilitysa.org.za/TreatmentGuidelines/ReproductiveMedicine.asp
Blood and blood products	National Blood Committee (not in operation since 2008)	Yes SANBS and WPBTS websites & other
Cell-based therapy	South African Stem Cell Transplantation Society (SASCTS)	Yes; none on website http://www.stemcell.org.za/index.htm
Genetic Services	Southern African Society of Human Genetics (SAHGS)	Yes http://www.sashg.org/documents.htm
Tissue banks	South African Tissue Bank Association (SATiBA)	Newly formed http://www.satiba.org.za
Forensic pathology and medicine	National Forensic Pathology Services Committee	Yes No website
	National Clinical Forensic Committee	In progress

Accreditation Committee of the International Society for Cellular Therapy (ISCT) and the European Society for Blood and Marrow Transplantation (EBMT)^[20] and the American Association of Blood Banks.^[21]

Economic considerations

Section 60 of the NHA, titled ‘Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes’ stipulates the following:

- (1) No person, except-
- (a) a hospital or an institution contemplated in section 58(l)(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 a blood product.
- (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, a gamete, blood or a 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.’

Any discussion on human tissue legislation (and in particular stem cells) needs to make a distinction between activities that involve altruistic donation of human material and those that result in commercial gain. Any commercial activity directly involving human material (including stem cells) that is provided on an altruistic basis by a voluntary donor should be run on a not-for-profit cost recovery basis with publicly accessible accountability of how resources are managed. Other activities that involve human stem cells directly or indirectly and that are not based on the principle of an altruistic donation should be permitted to run on a for-profit basis. This includes storage and manipulation of stem cells for individuals who pay for the service on a fee-for-service basis, as well as all related activities including but not limited to the development and manufacture of materials for tissue culture (equipment, plastic ware, reagents including growth factors) and medical devices (including those required for stem cell harvesting and purification). It is important to note that the NHA prohibits the sale of and trade in stem cells, as this would be tantamount to ‘organ trafficking’ even though a stem cell(s) is not an organ *per se*. Furthermore, an authorised institution may only receive payment in respect of the acquisition, supply, importation or export of stem cells.

Although it is clear that a public cord-blood bank in which stem cells are altruistically donated must be a not-for-profit company run on the basis of cost-recovery, the indiscriminate application across the board of a not-for-profit rule in all matters pertaining to human tissues and stem cells, in particular, would severely stifle the rollout of stem cell therapies and related research in SA. The cell therapy industry is still in its infancy in this country, and preventing the establishment of for-profit companies would stifle the implementation of new cell therapy technologies as well as all future research activity into stem cells in the biotechnology sector. The latter is emphasised in the Bioeconomy strategy released in 2014 by the Department of Science and Technology.^[22] The therapeutic promise of stem cells has driven huge investment globally into the cell therapy industry. Without this investment, and the return it promises to bring to its investors, progress in the field would be significantly stunted.

Conclusion

Legislation in its broadest sense should be seen as a permanent work-in-progress requiring ongoing review. The importance of feedback from all sectors concerned including patients and their healthcare providers cannot be overemphasised.

Legislation in its broadest sense is needed:

- To ensure that pre-clinical studies and well controlled clinical trials have been conducted prior to introduction of cells into patients:
 - to ensure that the purported therapeutic effect is real
 - to ensure that there are no serious side effects
- To ensure that work involving material that will be (re)introduced into patients is conducted in an accredited institution under strictly controlled conditions.

The absence of appropriate legislation:

- Permits (and even encourages) the emergence of medically unsound and unethical practices that may be associated with the exploitation of emotionally vulnerable patients.
- Dissuades the transfer into SA of much-needed skilled individuals, intellectual property and foreign investment in the cell-therapy field.

In SA we have 'need' from the perspective of the patient, 'ability' from the perspective of the medical, scientific and business communities, and 'material' both from a research and therapeutic perspective. Legislation in SA in the human tissue field, and in stem cells in particular, is still in its infancy. This provides healthcare professionals and researchers with an opportunity to assist the legislator in drafting legislation that is both modern and appropriate to the diverse needs of the SA population. However, while legislation is necessary to protect patients and their healthcare providers, it should not be stifling or obstructive.

With regard to clinical trials, these need to be registered with the Medicines Control Council (MCC) and would include any form of therapy that is unproven or experimental in nature. Protocols need to be examined by a registered institutional ethics committee (peer reviewed). Finally, patients should not have to pay for treatments that are unproven or experimental.

Based on the broad outline provided above and in mapping out the process ahead, it is recommended that:

- An oversight and coordinating committee be established, which includes government, academia and the private sector, to work with groups in each of the seven areas delineated above together with the legislator, to constantly monitor new developments in order to be able to be agile in response thereto.

- The current legislation be revised to close regulatory gaps, remove inaccuracies and redundancy and to ensure that all legislation is harmonised.

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