No. R. 376 **4 May *2007***

NATIONAL HEALTH ACT, **2003**

REGULATIONS **RELATING** TO HUMAN **STEM** CELLS

The Minister of Health intends, in terms of section 68 of the National Health Act, 2003 (Act **No.** 61 of 2003), to make the regulations in the schedule.

Interested persons are invited to submit written comments on the proposed regulations, or any representations they may wish to make in regard thereto, to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for the attention of the Cluster Manager: Non-Communicable Diseases) within three months from the date of publication of this notice.

SCHEDULE

CHAPTER 1

Definitions

1. In these regulations, ***"the Act"*** means the National Health Act, 2003 (Act No. 61 of 2003), and any word or expression to which a meaning **has** been assigned in that Act, shall have that meaning and unless the context indicates otherwise:

"competent person" means –

(a) in the case of stem cells retrieval from a deceased person, a medical practitioner or person who by qualification is competent to remove the specific stem cells; or

(b) in the case of stem cells retrieval from a living person, a medical practitioner who by qualification **is** competent to remove the specific stem cells;

"clone" means an organism that is a genetic copy of an existing organism;

"distribution" means transpottation and delivery of tissue and cells intended for human applications;

"donor" means a person who has donated tissue in terms of the Act;

"embryonic stem cells" means specialized or undifferentiated cells that can divide indefinitely in culture and can develop into specialized or undifferentiated cells;

"high risk family" means a family with history of genetic or haematological disorder;

"human application" means the use of tissues or cells on or in a human recipient and extracorporal applications;

"inspector of anatomy" means the inspector of anatomy as contemplated in the Regulafions Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes;

"investigating officer" means the investigating officer as contemplated in the Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes, ;

"muffipotent" means a cell that is specialized for specific tissue;

"pluripotent" means a cell that is able to develop into most tissues of an organism;

"procurement" means a process by which tissue or cells are made available;

"processing" means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

'preservation" means the use of chemical agents, alterations in environment conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissue;

'quarantine" means to isolate retrieved tissue or cells physically or by other means whilst awaiting a decision on their acceptance or rejection;

"authorised organisation, institution or person" means an organisation, institution or person authorised in terms of regulation 3(3)(a) to conduct the activities referred to in regulation 2(1)(a), (b) or (c);

"responsible person" means any person registered in terms of the Health Professions Act, 1974 (No 56 of 1974) and who is in charge of the activities referred to in regulation 2(1)(a), (b) and (c);

"serious adverse event" means any untoward occurrence associated with the procurement, testing. processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, death or life threatening, disabling or incapacitating condition for patients or which might results in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the donor or in the recipient associated with the

procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity;

"stem ***cell"*** means any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell including haemopoietic progenitor cell, umbilical cord progenitor cell, haemopoietic progenitor cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell,;

"storage" means maintaining the product under appropriate controlled conditions until distributed;

"totipotent" means a cell that is able to form an entire organism;

"transplantation transmittable disease" means a disease that can be transmitted by the transplantation of tissue or a tissue product donated by a person, into the body of another person, including a genetic disease.

Use of stem cells

2. (1) No person, shall -

(a) acquire or import human stem cells from any living or deceased person;

(b) preserve, screen, test, process. store, separate, label, pack, supply or distribute or export or in any other manner dispose of human stem cells whether in its original form or in any altered form; or

(c) release any stem cell products for therapeutic use, unless-

(i) it is authorised in terms of section 54 of the Act;

(ii) laboratory tests, according to latest scientific information for infectious agents and genetic diseases which may cause transplantation transmitted diseases, for the following, have, with informed consent, been completed and the results of the tests on each stem cell are available;:

- Syphilis
- Hepatitis B
- Hepatitis C
- Human Immunodeficiency Virus type 1 and 2

- p24 HIV antigen
- Genetic disease traits
- Card blood gases before umbilical cord stem cells are harvested

(d) use stem cells or its products for therapeutic, research or educational purpose unless it, he or she -

(i) is registered with the Department in terms of regulation 3(3)(a);

(ii) conducts any activity referred to in paragraph (a) or (b), as the case may be, in accordance with the provisions of these regulations:

(iii) has obtained informed written consent of the donor even in the case of residual tissue/cells; and

(iv) has obtained the donation voluntarily; and

(e) use stem cells for any reason other than therapeutic, teaching or research purposes.

(2) The provisions of subregulation (1) are not applicable to a person transporting human stem cells in the usual course of business as a carrier; if special transport requirements are adhered to.

Application for authorization

3. (1) A person desiring to be designated as an authorised institution shall apply for such authorisation to the Minister.

(2) The application referred to in subregulation (1) shall contain the following information:

(a) the name and nature of **the** applicant (whether an organization, institution, medical scientist, etc);
(b) location of the premises where business is to be conducted;
(c) an indication of how records and data shall be kept;
(d) the quality system to be used;
(e) details of the responsible person;
(9 qualifications and training for personnel;
(g) standing operating procedures of the applicant; and

(h) any other information the Minister may consider necessary for the consideration of the application.

(3) The Minister may, on application in terms of subregulation (1), authorise the applicant concerned as a stem cell establishment, subject to such conditions as the Minister may determine.

(4) An authorised stem cell establishment shall operate as a non-profit making entity.

(5) Only a health organisation, health institution, medical scientist or human biological scientist can apply for authorisation in terms of this regulation.

Suspension or withdrawal of authorisation

4. (1) If the Minister is of the opinion on the strength of an inspection, report and recommendation by an inspector of anatomy or an investigating officer that there are reasonable grounds to suspect that–

(a) any premises or equipment used by an authorised stem cell establishment are in any way hazardous to health;

(b) the stem cell establishment is not complying with any requirements, standards of practice, standard operating procedures or policies; or

(c) the rights of the donor or recipient are violated; and

(d) the stem cell establishment, after been afforded an opportunity by the inspector of anatomy or the investigating officer to rectify the situation referred to in paragraphs (a), (b) or (c), failed to rectify such situation,

the Minister may, suspend or withdraw the authorisation.

(2) The Minister, before suspending or withdrawing an authorisation as contemplated in subregulation (1), shall afford the stem cell establishment an opportunity to show cause why the authorisation should not be suspended or withdrawn.

(3) The suspension or withdrawal of authorisation in terms of this regulation shall have the effect that, the stem cell establishment shall cease to carry out any activities referred to in regulation 2(1) (a), (b) and (c).

Keeping of records and reporting obligations

5. (1) The stem cell establishment shall keep-

(a) a register of stem cell donors in which it shall be entered at least the following particulars pertaining to each stem cell donor from whose body the stem cell establishment has obtained stem cells:

(i) The surname, first name and initials or the other names;
(ii) the gender;
(iii) the date of birth or approximate age if the former is not available,
(iv) identity number;
(v) the address;
(vi) the nature and quantity of the stem cells concerned;
(vii) reason for acquiring the stem cells; and
(viii) a record of the written informed consent;

(b) a record of stem cell donations in which it shall be entered the following information:

(i) a unique identifiable code which will be traceable to the stem cell donor while protecting the donor's anonymity;
(ii) the date and place of retrieval from the body of the relevant donor;
(iii) the name of the competent person who removed the stem cell from the relevant donor;
(iv) the name and address of the organisation, institution or person from whom the stem cell concerned was received;
(v) the date on which the stem cell concerned was received from the organisation, institution or person referred *to* in (iv);

(vi) the results of tests for transplantation transmittable diseases and/or genetic traits;

(vii) the results of tissue typing if available;

(viii) whether any serious adverse events ***or*** reaction or death was reported following upon the treatment and the serial number of the entry in respect of the reaction or death as recorded in the register of adverse events or reactions, including transplantation communicable or genetic transmittable diseases;

(ix) if the stem cells was condemned or discarded –

(aa) the date on which it was condemned or discarded;

(bb) the reason for which it was condemned or discarded;

(cc) the method used for discarding; and

(x) any stem cells rejected and the reasons for the rejection:

(c) a record of statistics in respect of stem cells, in which *it* shall **be** entered at least the following information in respect of all the stem cells donations and the supply of such stem cells by the stem cell establishment over each month:

(i) the number of stem cell donors and recipients;

(ii) the type and total number of stem cells supplied;

(iii) the names and addresses of the organisations. institutions or persons to whom the cell was supplied (public and private);

(iv) the number of cells which were condemned or discarded and the reason for which they were condemned or discarded:

(v) the nature and number of cells which gave results indicative of microbial contamination or genetic disease;

(vi) the number of serious adverse events or reactions, including transplantation communicable or genetic transmittable diseases, or deaths entered in the register referred to in paragraph (d); and

(vii) the number of stem cells in storage and the period for such storage.

(d) a system in place to receive, investigate, register and transmit information to the Director General about serious adverse events and

reactions which may influence the quality and safety of stem cells and which may be attributed to the procurement, testing, processing, storage and distribution of stem cells as well as any serious adverse reaction observed during or after clinical application which may be linked to quality and safety of cells;

(e) an accurate, rapid and verifiable procedure in place which will enable it to recall from distribution any product(s) which may be related to a serious adverse events or reaction.

(2) The stern cell establishment must -

(a) inform the Director-General of any change in its name, address, medical director or responsible person;

(b) provide the inspector of anatomy for the area in which the tissue or stem cell was supplied immediately with the information referred to in subregulation(1)(c); and

(c) inform the Director-General in writing if it no longer intends to carry out the activities referred to in regulation 2(1)(a) and (b).

(3) The inspector of anatomy shall submit a monthly report on the reports received in terms of subregulation (2) (b) to the Director-General.

(4) Any payment made according to section **60** (1) (a) and (b) of the Act must be recorded and this includes the amount paid, the person to whom payment was made, the reason for payment and the person who made the payment, according to Section 60(4)(a) of the Act.

(5) Strict confidentiality must be observed by all employees of the stem cell establishment with regard to all information in its possession pertaining to tissue or stem cell donors and recipients.

6. The Director-General shall establish and maintain a publicly accessible database of stem cell establishments specifying the activities for which they have been authorised.

Stem cells for later therapeutic use

7. Stem cells obtained for later therapeutic use must only be obtained from high risk families.

Additional powers and duties of an inspector of anatomy or investigating officer

8. (1) An inspector of anatomy or investigating officer may, in addition to exercising the powers referred to in the Regulations Regarding the General Control of Human Bodies, Tissue, Blood, Blood *Products* and Gametes, as far as tissue or any tissue product or any matter relating thereto is concerned –

(a) take samples, or direct that samples be taken and forwarded or delivered in such quantities as she or he may consider necessary for testing purposes;

(b) mark or seal any container of stem cells or any device, test reagent or substance;

(c) request information or registers from the management of the stem cell establishment and interrogate any member of the staff of the stem cell establishment or related persons in connection with –

(i) any premises, equipment or methods used by the stem cell establishment;

(ii) any tissue or tissue product or any test reagent or substance referred to in these regulations; or

(iii) any applicable standard operating procedures;

(d) place under embargo or seize any tissue or tissue product or documentation if in her or his opinion it may produce evidence of the commission of an offence in terms of the Act and these regulations.

(2) An inspector of anatomy or an investigating officer shall exhibit the written authority by virtue of which she or he is authorised to act as such to any person affected by the exercise or performance of any power, duty or function under these regulations when called upon to do so by that person.

Inspection and control measures

9. A stem cell establishment shall be inspected at least once every year to ensure that it complies with these regulations.

Traceability

10. A stem cell establishment must ensure that-

(1) All its activities referred to in regulation 2(1)(a), (b) and (c) can be traced from donor to the recipient and vice versa.

(2) it has a unique donor identification system which assigns a code to each donation and to each products associated with it.

(3) all stem cells are identified with a label that contains the information or references allowing a link to the information referred to in regulation 5(1)(b).

(4) data necessary to ensure traceability at all stages is kept for a minimum of 30 years after donation or clinical use and such data storage may be in electronic form.

Data protection and confidentiality

11. (1) A stem cell establishment shall ensure that all data, including genetic information, collated within the scope of these regulations and to which third parties have access remain confidential at all times.

(2) For the purposes of subregulation (1), stem cell establishment shall ensure that:

(a) data security measures are in place, as well as safeguards against any unauthonsed data additions, deletions or modifications to donor files or referral records and transfer of information;

(b) procedures are in place to resolve data discrepancies: and

(c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.

Quality and safety of stem cells

12. (1) A stem cell establishment shall take necessary measures to ensure that-

(a) an updated quality system based on the principle of good practice is put in place;

(b) the quality system referred to in paragraph (a) includes at least the following documentation:

(i) standard operating procedures (SOP);
(ii) guidelines;
(iii) training and reference manuals;
(iv) reporting forms;
(v) donor records; and
(vi) information on the final destination of stem cells.

(c) the documentation referred to in paragraphs (a) and (b) is available for inspection by the inspector of anatomy or an investigating officer.

Responsible *person*

13. (1) A responsible person, who shall be a medical scientist, shall be responsible for:

(a) ensuring that stem cells in the establishment are handled according to these regulations;
(b) providing information to the Director-General as required in terms of these regulations; and
(c) compliance with the requirements of these regulations.

(2) A stem cell establishment that changes a responsible person shall immediately inform the Director-General of that fact.

Personnel

14. Personnel directly involved in activities referred to in regulation 2(1)(a), (b) and (c) and regulation **12** in the stem cell establishment shall be qualified to perform such tasks and shall be provided with relevant training.

Stem cell reception

15. Stem cells shall be kept in quarantine until such time as the requirements relating to donor. information and test results have been met.

Stem cell processing

16. (1) A stem cell establishment shall include in its standard operating procedures and guidelines-

(a) all processes that affect quality and safety and ensure that these are carried out under controlled conditions;

(b) special provision for the handling of stem cells to be discarded, in order to prevent the contamination of other cells, processing environment or personnel.

(2) Any modification to the process used in the preparation of stem cells shall also meet the criteria laid down in its standard operating procedures.

(3) The stem cell establishment shall ensure that the equipment used, the working environment and process design, validation and control conditions are in accordance with its standard operating procedures.

Stem cell storage conditions

17. (1) A stem cell establishment shall ensure that all procedures associated with the storage of cells are documented in the standard operating procedures and guidelines and that the storage conditions comply with the requirements referred to therein.

quality and safety

(2) A stem cell establishment shall have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored stem cells are transferred to other authorised stem cell establishments.

Labelling, documentation and packaging

18. A stem cell establishment shall ensure that labelling, documentation and packaging conform to its standard operating procedures.

Distribution

19. A stem cell establishment shall ensure the quality of stem cells during distribution is not compromised.

Relationship between *stem* cell establishments and third *parties*

20. (1) A stem cell establishment shall evaluate and select third parties on the basis of their ability to meet the requirements standards laid down in these regulations.

(2) A stem cell establishment shall enter into written agreements with a third party each time an external activity takes place which influence the quality and safety of stem cells processed in cooperation with such a third party, and in particular in the following circumstances:

(a) where a stem cell establishment entrusts one of the activities in regulation 2(1)(a), (b) and (c) to a third party;

(b) where a third patty provides goods and services that affect stem cells quality and safety assurance, including their distribution:

(c) where a stem cell establishment distributes stem cells obtained by a third patty;

(3) A stem cell establishment shall keep a complete list of the agreements referred to in this regulation.

(4) Agreements between stem cell establishments and third parties shall specify the responsibilities of the third parties and detailed procedures.

(5) A stem cell establishment shall provide copies of agreements with third parties on request to the Director-General, the Inspector of anatomy or an investigating officer.

Offences and penalties

21. Any person who contravenes or fails to comply with any provision of these regulations shall be guilty of an offence and liable on conviction to a fine or imprisonment for a period not exceeding five years.

Commencement

22. These regulations shall come into operation six months from the date of publication

J. Radebe

MINISTER J.T. RADEBE, MP
ACTING MINISTER OF HEALTH