

No. R. 183

2 March 2012

NATIONAL HEALTH ACT, 2003**REGULATIONS RELATING TO STEM CELL BANKS**

The Minister of Health has, in terms of section 68 of the Health Act, 2003 (Act No 61 of 2003), made regulations in the Schedule.

SCHEDULE**Definitions**

1. In these regulations, any word or expression to which a meaning has been assigned in the Act shall have that meaning and unless the context otherwise indicates-

“Act” means the National Health Act, 2003 (Act No 61 of 2003);

“Council” means the National Health Research Ethics Council referred to in section 72 of the Act;

“distribution” means a process that includes receipt of a request for stem cells, selection and inspection of appropriate stem cells, and inspection, and subsequent shipment and delivery of stem cells to another stem cell bank, stem cell distribution intermediary, or stem cell dispensing service;

“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 tissue or blood products or stem cells;

“processing” means all procedures involved in the preparation, manipulation, preservation and packaging of tissues, blood products or stem cells intended for human applications;

“quarantine” means the isolate retrieved tissue, or blood products or stem cells physically or by other means whilst awaiting a decision on their acceptance or rejection;

“responsible person” means a person who is authorised to be a medical director of a stem cell bank;

“stem cells” means cells that have both the capacity to self-regenerate as well as to differentiate into mature specialised cells;

“third party” means an organisation or institution commissioned by a stem cell bank to provide services that the stem cell bank cannot perform;

“transplantation transmittable disease” means a disease that can be transmitted by the transplantation of 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) remove, acquire or import human stem cells from any living or deceased person; or
 - (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) these activities are authorised in terms of section 54 of the Act; and
 - ii) laboratory tests for the following infectious agents which may cause transplantation transmitted diseases have been completed and the results of each are available:
 - Syphilis
 - Hepatitis B
 - Hepatitis C
 - Human Immunodeficiency Virus type 1 and 2.
- (2) Where stem cells are for autologous use, the tests referred to subregulation (1) (c) (ii) may not be required;
- (3) No person shall use stem cells or its products for therapeutic, research or educational purpose unless he or she
- i. is authorised with the Department in terms of regulation 3(3)(a);

- ii. conducts any activity referred to in sub-regulation (1) (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, blood or blood products; and
 - iv. is sure that the donor has donated voluntarily and it documented as such;
- (4) The provisions of subregulation (1) are not applicable to a person transporting human tissue, blood or blood products in the usual course of business as a carrier, if special transport requirements are adhered to.

Application for authorisation

3. (1) An application for authorisation shall be made to the Director-General;
- (2) The application referred to in sub-regulation (1) shall contain the following information;
- (a) the name of the bank;
 - (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 management system to be used;
 - (e) details of the responsible person;
 - (f) any other information the Director-General may consider necessary for the consideration of the application;
- (3) The Director-General may, on application in terms of sub-regulation
- (a) request that the stem bank be investigated;
 - (b) Obtain such information as she or he deems necessary for the consideration of the application

- (c) authorise the applicant concerned as a stem cell bank subject to such conditions as the Director-General may determine.

Suspension or withdrawal of authorisation

- 4. (1) If the Director-General is of the opinion on the strength of a report and recommendation by a health officer that there are reasonable grounds to suspect that-
 - (a) any premises or equipment used by the stem cell bank are in any way hazardous to health;
 - (b) the authorised stem cell bank is not complying with any requirements, standards of practice, standard operating procedures or policies;
 - (c) the rights of the donor or recipient are violated; or
 - (d) the authorised stem cell bank after been afforded an opportunity by the health officer to show cause why the authorisation should not be suspended or withdrawn and the stem cell bank has failed to show such cause;
 - (e) the Director-General may, suspend or withdraw the authorisation.
- (2) the Director -General before suspending or withdrawing an authorisation as contemplated in sub-regulation (1), shall afford the authorised stem cell bank an opportunity to show cause why the authorisation should not be suspended or withdrawn; and
- (3) the suspension or withdrawal of authorisation in terms of this regulation shall have the effect that, the authorised stem cell bank shall cease to carry out any activities.

Keeping of records and reporting obligations

5. (1) The authorised stem cell bank shall keep-
- (a) a register of stem cell donors in which shall be entered at least the following particulars pertaining to each stem cell donor from whose body the authorised stem cell bank has obtained the stem cell:
 - (i) the surname, first name and initials or the other names;
 - (ii) gender;
 - (iii) unique identification number or other recognised identification number;
 - (iv) the date of birth or approximate age if the former is not available;
 - (v) the address;
 - (vi) the nature and quality of the stem cells donation 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 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 identity;
 - (ii) the date and place where the tissue was retrieved from the body of the relevant donor;
 - (iii) the name of the competent person who removed the stem cell donation from the relevant donor;

- (iv) the name and address of the stem cell bank/organisation or institution from whom the stem cell donation concerned was received;
 - (v) the date on which the stem cell donation concerned was received from the stem cell bank/organisation or institution referred to in (iv)
 - (vi) the results of tests for transplantation transmittable diseases and/or genetic traits if any is known;
 - (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, including transplantation communicable diseases;
 - (ix) any stem cells rejected, reasons for rejection;
 - (x) if the stem cells were condemned or discarded —
 - (aa) the date on which it was condemned or discarded;
 - and
 - (bb) the reason for which it was condemned or discarded;
 - (cc) the method used for discarding
 - (xi) long term outcomes of stem cell donation and transplants of the living donor and recipient;
- (c) a record of statistics in respect of cell donations, in which shall be entered at least the following information in respect of all the stem cell donations and the supply of such stem cell donation by the authorised stem cell bank over each month;

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- i) the number of stem cell donors and recipients;
 - ii) the type and total number of stem cells donations supplied;
 - iii) the names and addresses of the organisations, institutions or persons to whom the cell were supplied;
 - iv) the number of stem cell donations which were condemned or discarded and the reason for which they were condemned or discarded;
 - v) the nature and number of stem cells donation which gave results indicative of microbial contamination.
 - vi) the number of serious adverse events 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 which may have been influenced by the quality and safety of stem cells and which may be attributed to the procurement, testing, processing, storage and distribution of stem cells; and
- (e) an accurate, rapid and verifiable procedure is in place which will enable recall from distribution any product(s) which may be related to serious adverse events.
- (2) The authorised stem cell bank must –
- (a) inform the Director-General of any change in its name, address or a responsible person;

- (b) provide the health officer for the area in which the stem cell donation were supplied immediately with the information referred to in subregulation (l)(c); and
 - (c) inform 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 health officer shall submit a monthly report on the reports received in terms of subregulations (2) (b) to the Director-General;
- (4) Any payment made according to section 60 (1) (a) and (b) of the Act must be recorded - the amount paid, to whom payment was made, reason for payments and who made payment, according to Section 60 (4) (a) of the Act;
- (5) Strict confidentiality must be observed by all employees of the authorised stem cell bank with regard to all information pertaining to stem cells donors and recipients; and
6. The Director-General shall establish and maintain an accessible database of authorised stem cell institutions or organizations, specifying the activities for which they have been authorised.

Additional duties of the health officer

7. (1) A health officer may, as far as stem cells or any matter relating thereto is considered –
- (a) take samples, or direct that such samples be forwarded or delivered to whom so ever or wherever she or he deems fit, in such

quantities as she or he may consider necessary and adequate for testing purposes, of tissue or any tissue product or of any device or test reagent or other material used in the testing or preparation of such tissue or tissue product;

(b) mark or seal any container with stem cell or any device, test reagent or substance;

(c) request information or registers from the management of the authorised stem cell bank and interrogate any member of the staff of the authorised stem cell bank in connection with —

- i) any premises, equipment or methods used or being used by the authorised stem cell bank;
- ii) any tissue or tissue product or any test reagent or substance referred to in these regulations; or
- iii) any applicable standards operating procedures;

(d) place under embargo or seize any stem cells; or

(e) documentation if in her or his opinion it may produce evidence of an offence in terms of the Act and these regulations.

(2) a health officer shall exhibit the written authority by virtue of which she or he was authorised, to any person affected by the exercise or performance, of any power, duty or function under the Act, when called upon to do so.

Inspection and control measures

8. A stem cell bank shall be inspected at least once every year to ensure that it complies with these regulations and any other relevant requirements.

Traceability

9. Stem cells banks must ensure that-
- (a) all its activities referred to in regulations 2 (1)(a),(b) and (c) can be traced from donor to recipient and vice versa;
 - (b) it has a unique donor identification system which assigns a code to each donation and to each products associated with it;
 - (c) all stem cells be identified with a label that contains the information or references allowing a link to the information referred to in regulation 5(1) (b);
 - (d) data necessary to ensure traceability at all stages is kept for a minimum of 30 years after donation or clinical use and such data may be in electronic form.

Data protection and confidentiality

10. An authorised stem cell bank shall -
- a) ensure that all data, including genetic information, collated within the scope of this regulation remain confidential at all times.
 - b) for that purpose of subregulation (1), an authorised stem cell bank shall ensure that:
 - (i) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records and transfer of information.
 - (ii) procedures are in place to resolve data discrepancies;
 - (iii) no unauthorised disclosure of information occurs, whilst

- guaranteeing the traceability of donations; and
(iv) anonymity and privacy of donors are protected

Quality and safety of stem cells

11. (1) An authorised stem cell bank shall take necessary measures to ensure that-
- a) an updated quality control and safety system based on the principle of best laboratory and, manufacturing practice is put in place;
 - b) the quality control and safety 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 the stem cells
 - c) the documentation referred to in paragraph (a) and (b) is available for inspection by the health officer.

Responsible person

12. (1) Responsible persons shall be responsible for:
- (a) ensuring that stem cells in the authorised stem cell bank be handled according to these regulations.
 - (b) providing information to the Director-General as required in terms of this regulation; and

(c) compliance with the requirements of these regulations.

(2) where there is a change of the responsible person, an authorised stem cell bank shall immediately inform the Director-General of that fact.

Stem cell quarantine

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

Stem cell processing

14. (1) An authorised stem cell bank shall include in their standard operating procedures and guidelines:

- (a) all processes that affect quality, safety and controlled conditions; and
- (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 procedure.

(3) an authorised stem cell bank 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 condition

15. An authorised stem cell bank shall -

- (1) ensure that all procedures associated with the storage of cells are documented in standard operating procedures and that the storage conditions comply with the requirements referred to in standards of practice.
- (2) have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored cells shall be transferred to other authorised stem cell banks.

Labeling, documentation and packaging

16. An authorised stem cell bank shall ensure that –

(1) labeling, documentation and packaging conform to the standard operating procedures;

(2) all labeling claims shall be clear, accurate, substantiated, and not misleading;

(3) the following information shall be included on the container label unless space limitations require use of a corresponding insert:

- i) descriptive name of the cells and/or tissue;
- ii) unique identification code for traceability purposes;
- iii) name(s) and address(es) of stem cell bank(s) responsible for determining donor suitability, processing and distribution;
- iv) expiration date (if applicable);
- v) acceptable storage conditions;
- vi) disinfection or sterilisation procedure utilized (if applicable);
- vii) preservative and/or method of preservation (if applicable)
- viii) quality of cells and/or stem cells expressed as volume, weight, dimensions, if applicable;
- ix) potential residues of processing agent(s) solutions viii) preservative and/or method of preservation (if applicable); and
- x) sterility status.

Distribution

17. (1) An authorised stem cell bank shall ensure the quality of stem cells during distribution is not compromised; and
- (2) the Minister will determine allocation of stem cells.

Relationship between authorised stem cell banks and third parties

18. An authorised stem cell bank shall -
- (1) evaluate and select third parties on the basis of their ability to meet the required standards laid down in these regulations.
- (2) establish written agreements with the third party each time an external activity takes place which influence the quality and safety of stem cells processed cooperation with a third party, and in particular in the following circumstances:
- (a) where an authorised stem cell bank entrusts one of the activities in 2(l)(a) and (b) to a third party;
- (b) where a third party provides goods and services that affect stem cells quality and safety assurance, including their distribution;
- (c) where an authorised stem cell bank distributes stem cells harvested by third party;
- (d) an authorised stem cell bank shall not provide services to a third party which is not accredited by the South African Accreditation System;

- (3) keep a complete list of the agreements they have established with third parties;
- (4) ensure that agreements between authorised stem cell bank and third parties shall specify the responsibilities of the third parties and detailed procedures;
- (5) provide copies of agreements with the third party on request to the Director -General;

Appeals

19. (1) A stem cell bank who applied for authorization may appeal in writing to the Minister against any decision made by the Director General in terms of any provision of these regulations in respect of such stem cell bank as the case may be;
- (2) an appeal in terms of sub-regulations (1) must be lodged within fourteen (14) days of the receipt of a notice of such decision by the stem cell bank, and must clearly state:
 - (a) against which decisions such appeal is lodged; and
 - (b) the grounds on which such appeal is based.
- (3) any appeal in terms of these regulations shall be lodged with the Director General, who shall submit it to the Minister with his or her reasons for the decision against which the appeal is being lodged and
- (4) the Minister may confirm, amend or revoke a decision taken the Director General in terms of the provisions of these regulations and inform the stem cell bank, as the case may be, in writing of his or her decision.

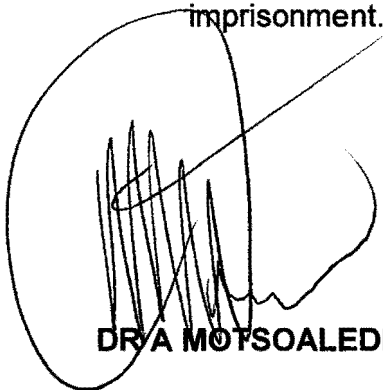
Delegations

20. (1) The Director General may subject to such conditions she or he may determine, in writing delegate, whether general, in particular case or in cases of a particular nature in the Department any power conferred upon her or him by or under these regulations; and

(2) the Director General shall not be divested of a power delegated by her or him under sub-regulation (1) above, and may alter or set aside any decision by an officer taken in the exercise of a power so delegated

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 10 years or to both fine or such imprisonment.

A handwritten signature in black ink, consisting of several vertical strokes and a horizontal line at the bottom, enclosed within a hand-drawn oval. A diagonal line is drawn across the signature from the top right to the bottom left.

DR A MOTSOLEDI

MINISTER OF HEALTH

DATE: 1/3/2012