
GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 8

5 January 2007

DEPARTMENT OF HEALTH

NATIONAL HEALTH ACT, 2003

REGULATIONS REGARDING ARTIFICIAL FERTILISATION AND RELATED MATTERS

The Minister of Health intends, in terms of section 90(1), read with section 68(1) of the National Health Act 2003 (Act No. 61 of 2003), and after consultation with the National Health Council, to make the regulations in the Schedule.

interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General: Health, Private Bag X828, Pretoria, 0001 (for attention of Ms Lineo Motopi: Human Genetics), within three months of the date of publication of this notice.

SCHEDULE

Definitions

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

“artificial fertilisation” means conception resulting from artificial insemination or *in vitro* fertilisation of a woman;

“artificial insemination” means the placing of male gametes (sperm) into the female reproductive tract by means other than copulation;

“blasfocyst” means a pre-implantation embryo consisting of an outer layer, which forms the placenta and a 30 to 200-cell inner cell mass, which develops into the foetus;

“cell” means the basic structural and functional unit in people and all living things. Each cell is a small container of chemical and water wrapped in a membrane;

“central data bank” means an electronic bank established by the Director General into which all information regarding gamete and embryo donations are stored;

“competent person” for an artificial fertilisation program means a medical practitioner, clinical technologist, medical technologist or medical scientist registered with the Health Professions Council of South Africa (HPCSA) with expertise as follows –

- (a) a gynaecologist with training in reproductive endocrinology, particularly in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle;
- (b) a gynaecologist with training in pelvic reparative (infertility) surgery and laparoscopic and ultrasound-guided oocyte retrieval techniques;
- (c) an ultrasonographer with specialised training in gynaecologic sonography who provides the monitoring of follicular development;

- (d) an expert in male reproduction (andrology) with special training in semenology;
- (e) an expert in male reproductive surgery;
- (f) an expert in the organisation and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques;
- (g) an expert in gamete and embryo cryopreservation techniques; or

(h) an expert in gamete biology and experience in microoperative techniques;

“deceased” means somatic death where the death can be certified, i.e. where there is cessation of circulation and respiration, including loss of corneal reflexes, the eyeballs become flaccid, and the pupils are fixed and dilated;

“donation” means the donation of any specific biological material in accordance with sections 55(a), 62(1)(a), (2) and (3) of the Act;

“embryotransfer” means the placing of the embryo into the uterus or fallopian tube of the recipient and zygote transfer has a corresponding meaning;

“export” means to send or transport human biological material from South Africa by any means;

“gamete donor” means a living person from whose body a gamete or gametes are removed or withdrawn, for the purpose of artificial fertilisation;

“import” means to bring or carry in, human biological material into South Africa by any means;

“informed consent” means an agreement by which a participant, donor or health care user voluntarily confirms his/or her willingness to participate in research, donation or treatment, after understanding all aspects of the research, donation or treatment that are relevant to his/or her decision;

“in vitro fertilisation” is the process of fertilisation an ovum (egg) with a male sperm outside the body of a recipient;

“prescribed institution” means an institution such as university, private laboratory or assisted reproductive facility, accredited by the South African Accreditation Systems (SANAS) to perform artificial fertilisation and related technologies;

“recipient” means a female person in whose reproductive organs a male gamete or gametes are to be introduced by other than natural means; or in whose uterus/womb or fallopian tubes a zygote/zygotes or embryo/embryos is/are to be placed for the purpose of human reproduction;

“register” means a register referred to in regulation 14(1);

“section” means a section of the Act;

“serious genetic condition” means a genetic condition, which compromises functional physical or mental ability and may sometimes be lethal;

“stimulation” means any process, method or procedure used to facilitate the withdrawal or removal of a gamete or gametes;

“spouse” means a partner in a marriage, by an alliance in terms of an Act of the Parliament or by customary law that constitutes a marriage; and

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

CHAPTER 1

Application

2. These regulations are only applicable to withdrawal of gametes from living persons.

REMOVAL OR WITHDRAWAL OF GAMETES AND RELATED MATTERS

Removal or withdrawal and storage of gametes

3. (1) No person, except a competent person, may remove or withdraw a gamete or cause a gamete to be removed or withdrawn, from the body of a gamete donor for the purpose of artificial fertilisation.
- (2) Once gametes are removed in terms of subregulation (1), they shall be stored in a frozen state.

Compensation in respect of the withdrawal or removal of gametes

4. A person from whose body a gamete has been removed or withdrawn may be reimbursed for any reasonable expenses incurred by him or her in order to donate a gamete as contemplated in section 60(4)(a) of the Act.

Establishment of a Central Data Bank

5. The Director General shall establish an electronic data bank into which all information regarding gamete(s) and embryo(s) donations are stored.

Restriction on donation of gametes

6. A competent person –
 - (a) shall not remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of a gamete donor if the competent person has information or suspects that a maximum of five children have been conceived through the artificial fertilisation using the gametes of that gamete donor;
 - (b) where the gamete donor has conceived five children as contemplated in paragraph (a), shall inform that gamete donor that she or he may not make any further donation of gametes in the State; and
 - (c) must immediately relay all the information relating to such gamete donor, the removal or withdrawal of a gamete and the artificial fertilisation, to the central data bank.

Prerequisites for removal or withdrawal of gametes

7. A competent person who intends to remove or withdraw a gamete, or cause a gamete to be removed or withdrawn from the body of a gamete donor, shall, before such removal or withdrawal –
- (a) ensure that if a gamete donor file has not previously been opened in respect of that gamete donor, open such a gamete donor file, to which a unique identification number shall be allocated in respect of the gamete donor;
 - (b) ensure the information obtained in paragraph (a) is submitted to the central data bank;
 - (c) in the case of a known donor, ascertain from the central data bank that a maximum of five children have not been conceived through the artificial fertilisation of a person with the gametes of that gamete donor;
 - (d) obtain a signed statement from the gamete donor stating whether the gamete donor has previously made a donation of gametes and, if so, where and when that donation of gametes took place;
 - (e) obtain an informed consent from the gamete donor to –
 - (i) to a physical examination and questioning by a competent person;
 - (ii) that a competent person may remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of the gamete donor for the purpose of such testing, analysing or other processing of that gamete as the competent person may deem necessary;
 - (iii) to the particulars contemplated in regulation 8(1)(a)(ii), (iii) and (iv), (b), (c) and (f) being made available to the recipient and the competent person who is to perform the artificial fertilisation;
 - (iv) to the particulars contemplated in regulation 8(2)(c) being made available to the Director-General; and
 - (v) to the particulars contemplated in regulation 8(2)(c) being submitted to the central data bank.
 - (f) ascertain the age of the gamete donor;
 - (g) ascertain that the gamete donor has on two occasions, not more than three months apart and one month prior to that donation of gametes, undergone –
 - (i) medical tests for sexually transmissible diseases; and
 - (ii) a semen analysis, in the case of a male gamete donor;
 - (h) ascertain that in the case of a female gamete donor, the donor has undergone a gynaecological examination prior to stimulation for the withdrawal of gametes; and
 - (i) question such gamete donor concerning her or his family history, especially with regard to any possible genetic condition or carrier status and mental illness in respect of any child, brother, sister, parent or grandparent of such gamete donor.

Gamete donor files, availability of information and destroying of gametes

8. (1) The competent person must immediately record the following information and documents in the gamete donor's file before a gamete is removed or withdrawn-
- (a) the gamete donor's –
 - (i) full name, surname, date of birth and identity number;
 - (ii) age, height, mass, eye colour, hair colour, complexion, population group, nationality, sex, religion, occupation, highest educational qualification and fields of interest;
 - (iii) family history referred to in regulation 7(i); and
 - (iv) subject to regulation 6(a), wishes in respect of the number of artificial fertilisations for which her or his gametes may be used;
 - (b) the particulars of medical tests for genetically transmissible disorders or for infectious diseases, or genetic evaluation of the gamete donor;
 - (c) particulars of any evaluation of the psychological suitability of the gamete donor to donate a gamete;
 - (d) particulars of each donation of gametes made by the gamete donor, including the date on which the donation of gametes was made;
 - (e) the informed consent and documents contemplated in regulation 7(e);
 - (f) results of the tests and the analysis or examination contemplated in regulation 7(e) to (g); and
 - (g) any other relevant document or information that the competent person may request.
- (2) The competent person referred to in subregulation (1) –
- (a) shall retain the gamete donor file in safe-keeping and shall not destroy the file, except with the written permission of the Director General;
 - (b) shall make the particulars set out in subregulation (1)(a)(ii), (iii) and (iv), (b), (c) and (f), together with the identification number referred to in regulation 7(a), available to the recipient and the competent person who is to effect the artificial fertilisation of the recipient;
 - (c) shall furnish the Director-General before 31 January of each year with the following particulars regarding the preceding year in respect of the gamete donor:
 - (i) the identification number of the gamete donor file;
 - (ii) the number of donations of gametes, with the dates on which the donations were made; and
 - (iii) the number of children conceived through the artificial fertilisation of a person that have been born alive from the gametes of the gamete donor;
 - (d) shall not make the gamete donor file, or information therefrom, available to any person other than a person acting under her or his supervision, except in terms of legislation or a court order;

- (e) shall immediately, after, if it has come to her or his attention that a maximum of five children conceived through the artificial fertilisation have been born alive from the gametes of a specific gamete donor-
 - (i) make a conspicuous note to that effect in the gamete donor file;
 - (ii) ensure that this information is captured on the central data bank;
 - (iii) destroy all gametes donated by such gamete donor and any gametes that the competent person has in storage, unless the Minister consents to the competent person keeping those gametes; and
 - (iv) inform the donor of the actions taken as in terms of subparagraph (iii).
- (f) who wants to keep the gametes referred to in paragraph (e)(iii) –
 - (i) shall forthwith address a substantiated request including the informed consent document from the gamete donor to the Minister for her or his consent to keep the gametes; and
 - (ii) may refrain from destroying the gametes until the Minister notifies the competent person of her or his decision.

CHAPTER 2

ARTIFICIAL FERTILISATION, EMBRYO TRANSFER AND RELATED MATTERS

Place where and person who effects artificial fertilisation and embryo transfer

- 9.(1) Artificial fertilisation or embryo transfer must only be effected at an authorised or prescribed institution.
- (2) Authorised and prescribed institutions must have as members of a team, medical practitioners, medical scientists, clinical technologists or medical technologists registered with the Health Professions Council of South Africa with expertise as follows –
- (a) a gynaecologist with training in reproductive endocrinology, particularly in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle;
 - (b) a gynaecologist with training in pelvic reparative (infertility) surgery and laparoscopic and ultrasound-guided oocyte retrieval techniques;
 - (c) an ultrasonographer with specialised training in gynaecologic sonography who provides the monitoring of follicular development;
 - (d) an expert in male reproduction (andrology) with special competence in semenology;
 - (e) an expert in male reproductive surgery;
 - (f) an expert in the organisation and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques;
 - (g) an expert in gamete and embryo cryopreservation techniques; and

(h) an expert in gamete biology and experience in microoperative techniques where oocyte microoperative techniques are offered.

(3) Only a competent person may effect artificial fertilisation.

Control over artificial fertilisation, embryo transfer, storage and destroying of zygotes and embryos

10. (1) An artificial fertilisation or embryo transfer may only be effected after the competent person has –
- (a) notified the Director-General in writing of the name or names of the authorised or prescribed institution where she or he intends to perform such artificial fertilisation or embryo transfer; and
 - (b) in her or his possession a written approval of such intended artificial fertilisation or embryo transfer.
- (2) No gamete
- (a) that has not been imported, removed or withdrawn in terms of the provisions of the Act or these regulations;
 - (b) from a gamete donor of whom the results of the tests, analysis or examination referred to in regulation 7(e) to (g), as the case may be, are not available yet; or
 - (c) from a gamete donor younger than 18 years of age except in the case of a medical indication,
- may be used for artificial fertilisation.
- (3) A gamete removed or withdrawn from the body of a gamete donor shall not be used for artificial fertilisation if the competent person who intends effecting the artificial fertilisation knows or suspects that –
- (a) two or more pregnancies currently exist as a result of previous artificial fertilisations with the gametes of the gamete donor;
 - (b) the possibility exists that after the intended artificial fertilisation, more than two pregnancies may exist simultaneously as a result of artificial fertilisation with the gametes of the gamete donor; or
 - (c) a maximum of five children conceived through artificial fertilisation have already been born alive from the gametes of the gamete donor.
- (4) (a) A competent person shall not effect for the purpose of an *in vitro* fertilisation a zygote, except for embryo transfer, to a specific recipient and then only by the union of gametes removed or withdrawn from the bodies of –
- (i) such recipient and an individual male gamete donor; or
 - (ii) an individual male and an individual female gamete donor;
- (b) A zygote or embryo, referred to in paragraph (a) shall be stored in a frozen state in an authorised institution;

- (c) **A** competent person shall destroy a zygote or embryo, which she or he has in storage as soon as the recipient for whom that zygote or embryo has been effected conceives or as soon as it is decided not to go ahead with the embryo transfer into that recipient, unless –
 - (i) the competent person decides, and with the informed consent of the recipient, to store such zygote or embryo for a further period for the purpose of a subsequent embryo transfer to that recipient; or
 - (ii) the Minister consents in writing that the competent person –
 - (aa) may, with the informed consent of such recipient, use such zygote or embryo for transfer to another specific recipient; or
 - (bb) may, with the informed consent of such recipient, use such zygote or embryo for a purpose, other than embryo transfer, which purpose shall be stated by the Minister in that consent;
- (d) **A** competent person who for the purposes referred to in paragraph (c)(ii) (aa) wishes to transfer the zygote or embryo to another recipient or in terms of paragraph (c)(ii)(bb) use such zygote for another purpose –
 - (i) shall immediately address a request to the Minister for her or his consent; and
 - (ii) must refrain from destroying the zygote or embryo until the Minister notifies the competent person of her or his decision.

Requisites for artificial fertilisation and embryo transfer

11. **A** competent person intending to effect the artificial fertilisation or embryo transfer to a recipient shall, before effecting the artificial fertilisation or embryo transfer –
 - (a) ensure that if a recipient file has not previously been opened in respect of that recipient, open such a recipient file, to which a unique identification number shall be allocated in respect of the recipient;
 - (b) obtain an informed consent from the recipient –
 - (i) to a physical examination and questioning by a competent person;
 - (ii) that a competent person may remove or withdraw a gamete from the body of the recipient for the purpose of such testing, analysing or other processing of that gamete, as the competent person may deem necessary;
 - (iii) to the artificial fertilisation of, or embryo transfer to herself;
 - (iv) to the particulars contemplated in regulation 13(2)(c) being made available to the Director-General; and
 - (v) to the particulars contemplated in regulation 13(2)(c) being made available to the central data bank;
 - (c) ensure that –
 - (i) the gamete donor's particulars and wishes referred to in regulation 8(1)(a)(i) to (iv) are conformed with;
 - (ii) the recipient's particulars and wishes referred to in regulation 13(1)(a)(i) to (iii) are conformed with;

- (iii) if the recipient or the gamete donor could be a carrier of a serious genetic condition –
 - (aa) the recipient and the gamete donor are tested to determine whether they are such genetic carriers; and
 - (bb) if it is determined that both the recipient and the gamete donor are such carriers or the gamete donor is such a carrier, a gamete from that gamete donor is not used for the artificial fertilisation of or the embryo transfer to the recipient;
 - (iv) if, on account of the family history of the recipient or the gamete donor, the possibility exists that one of them is a carrier, or both of them are carriers of a genetically transmissible disorder, the recipient or gamete donor, as the case may be, is examined or tested to determine whether she or he is such a carrier, and –
 - (ua) if it is determined that the recipient is such a carrier, the recipient is informed about the implications thereof; or
 - (bb) if it is determined that the gamete donor is, or may probably be, such a carrier –
 - (aaa) a gamete from that gamete donor is not used for the artificial fertilisation of; or
 - (bbb) the competent person who has removed or withdrawn a gamete, or caused a gamete to be removed or withdrawn, from the body of that gamete donor is informed that the gamete donor is, or probably may be, such a carrier.
12. No more than three zygotes or embryos may be transferred to the recipient during an embryo transfer procedure, unless there is a specific medical indication to the contrary.

Recipient files and availability of information

13. (1) A competent person who effects the artificial fertilisation of or embryo transfer to a recipient shall immediately record or file the following particulars and documents in a recipient file referred to in regulation 11(a):
- (a) The recipient's –
 - (i) full name, surname, date of birth and identity number;
 - (ii) family history, especially with regard to possible carrier status for genetic and or mental disorders;
 - (iii) wishes in respect of the population group of which the gamete donor, whose gametes are to be used for the artificial fertilisation, should be a member and the religion, which the gamete donor should profess, as well as any other wish of the recipient concerning the gamete donor;
 - (b) particulars of medical tests done for sexually transmissible infectious or communicable diseases in respect of the recipient;
 - (c) particulars of genetic evaluation made in respect of the recipient;

- (d) particulars of an evaluation made of the psychological or social suitability of the recipient with a view to her artificial fertilisation;
 - (e) the written statement contemplated in regulation 10(4)(c)(ii) and the informed consent contemplated in regulation 11(b);
 - (f) any other relevant document or information that the competent person may obtain, including a document or information regarding a previous artificial fertilisation of or embryo transfer to the recipient;
 - (g) in the case of in vitro fertilisation or embryo transfer –
 - (i) the number of zygotes or embryos effected for the embryo transfer to the recipient;
 - (ii) the number of zygotes or embryos used for each embryo transfer procedure;
 - (iii) the number of zygotes or embryos in storage in terms of regulation 10(4)(b);
 - (iv) the number of zygotes or embryos used for purposes other than embryo transfer in accordance with regulation 10(4)(c)(ii)(bb); and
 - (iv) the number of zygotes or embryos destroyed in terms of regulation 10(4)(c).
- (2) The competent person referred to in subregulation (1) shall –
- (a) retain the recipient file in safe-keeping and shall not destroy the file, except with the written permission of the Director-General;
 - (b) not make the recipient file, or information therefrom, available to any person other than a person acting under her or his supervision, except where a law provides otherwise or a court so orders;
 - (c) furnish the Director-General and the central data bank before 31 January of each year with the following particulars regarding the preceding year in respect of the recipient:
 - (i) the identification number of the recipient file;
 - (ii) the date on which an artificial fertilisation of the recipient, was effected;
 - (iii) the number of *in vitro* fertilisations of the recipient effected;
 - (v) the particulars contemplated in subregulation (1)(g); and
 - (vi) the result of each procedure referred to in subparagraph (ii).

Recording of names of authorised institutions and competent persons in register and provisional deletion and deletion

14. (1) The Director-General shall keep a register with particulars of-
- (a) an authorised or prescribed institution in terms of section 54 of the Act, where artificial fertilisation or embryo transfer may be effected;
 - (b) a prescribed institution in terms of section 63 of the Act; and
 - (c) a competent person who effects such artificial fertilisation or embryo transfer.

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- (2) The Director-General shall delete from the register the name of –
- (a) a competent person who has died;
 - (b) a competent person who requests the Director-General in writing to remove her or his name from the register;
 - (c) a competent person who was found to have contravened or failed to comply with the provisions of these regulations; or
 - (d) an authorised or prescribed institution in the case where the owner, manager or person in charge of such institution requests the Minister to remove the name of such a place from the register.
- (3) (a) a competent person who has changed her or his name or address of practice; and
- (b) the person in charge of an authorised or prescribed institution, the name or address of which has been changed,
- shall within 30 days of such change inform the Director-General in writing of such change.
- (4) The Minister may –
- (a) after an inspection of an authorised or prescribed institution or any activity or process connected with artificial fertilisation of or embryo transfer to a recipient in or on such an institution;
 - (b) on the grounds of a report by any –
 - (i) health officer as referred to in section 80 of the Act; and
 - (ii) any other officer of the Department specifically so designated in terms of sections 77 and 78 of the Act;
 - (c) on the grounds of a complaint, charge or allegation of which she or he has knowledge or which may come to her or his notice in connection with such authorised or prescribed institution, activity or process and after any inspection or collection of information in connection with such complaint, charge or allegation that she or he may deem necessary or expedient;
 - (d) in the case where she or he is of the opinion that on or in such place conditions exist which are dangerous or harmful or likely to be dangerous or harmful to health,
- provisionally delete the name of such place from the register, and the Minister must in writing notify the person in charge of such authorised or prescribed institution accordingly.
- (5) Any notice referred to in subregulation (1) shall provide sufficient details of grounds premising the intended action by the Minister and shall draw such person's attention to the provisions of subregulation (3).
- (6) (a) The suspension of an entry made in terms of this section shall be entered in the central data bank and a note made thereof in the register; and

- (b) shall be valid until the danger or situation which gave rise to such suspension has, to the satisfaction of the Minister, been removed: provided that **if** such danger or situation is not removed or rectified within a period of three months from the date of notice contemplated in sub regulation (1), such authorised institution must be deleted from the register and may not perform artificial fertilisation or embryo transfer.

CHAPTER 3

GENERAL SUPPLEMENTARY PROVISIONS

Reporting of births

15. (1) (a) All births delivered after the conception through artificial fertilisation shall be recorded by the person in charge of the facility where such delivery has taken place, into the central data bank within 3 months of such birth.
- (b) The mother who gives birth shall ensure that the competent person who effected the artificial fertilisation of or embryo transfer is informed of such birth and recording of the information referred to in sub-regulation (2), within 30 days of such birth.
- (2) The information recorded in terms of subregulation (1) shall include, but not be limited to:
- (a) the date of birth;
 - (b) the unique identification number referred to in regulation 11(a); and
 - (c) any genetic disorder or birth defect in the child.

Reporting of disorders and mental illnesses

16. (1) **An** authorised institution that effected the artificial fertilisation of, or embryo transfer to, a recipient, shall, should it come to their notice that a child born as a result of the artificial fertilisation displays any genetic disorder or suffers from any mental illness –
- (a) determine if the cause of the disorder or mental illness can be traced back to the gamete donor or the recipient; and
 - (b) should the disorder or mental illness be traced back to the gamete donor, in writing, notify the authorised institution that effected the donation of gametes, of the disorder or mental illness, any tests carried out with regard to the disorder or mental illness, the results of the tests and their view on the disorder or mental illness.

- (2) A parent of a child referred to in sub regulation (1) shall, where it comes to her or his attention that the child displays any disorder or suffers from any mental illness, report the disorder or mental illness to the authorised institution that effected the artificial fertilisation.

Ownership of gametes, zygotes and embryos

17. (1) Before artificial fertilisation, the ownership of a gamete donated for the purpose of artificial fertilisation is vested -
- (a) in the case of a male gamete donor but -
 - (i) before receipt of such gamete by the authorised institution to effect artificial fertilisation by the authorised institution which removed or withdrew the gamete; and
 - (ii) after receipt of such gamete by the authorised institution that intends to effect artificial fertilisation in that institution.
 - (b) in the case of a male gamete donor for the artificial fertilisation of his spouse, in that male gamete donor; and
 - (c) in the case of a female gamete donor, for the artificial fertilisation of a recipient, in that female gamete donor.
- (2) After artificial fertilisation, the ownership of a zygote or embryo effected by donation of male and female gametes is vested -
- (a) in the case of a male gamete donor, in the recipient; and
 - (b) in the case of a female donor, in that recipient;

Prohibition of Disclosure of certain facts

18. No person shall disclose the identity of any person who donated a gamete or received a gamete, or any matter related to the artificial fertilisation of such gametes, or reproduction resulting from such artificial fertilisation.

Appeals

19. (1) (a) A person in charge of an authorised institution that was deleted from the register in terms of regulation 14(1), may within 14 days of receiving such decision, appeal in writing to the Minister against such decision. |
- (b) A copy of the appeal shall be sent to the Director General for his or her information and response if necessary.
- (2) An appeal in terms of sub regulation (1) shall be lodged within 14 days of the receipt of a notice of such decision by the authorized institution, and shall clearly state the grounds on which such appeal is lodged.
- (3) The Minister may then confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these regulations and thereafter

inform the person in charge of the enlisted place in writing of her or his decision.

Offences and penalties

20. Any person who contravenes or fails to comply with any provision of these regulations commits an offence and is liable on conviction to a fine or imprisonment for a period not exceeding five years, or to both such fine and imprisonment.

Delegations

21. (1) The Director-General may, subject to such conditions he or she may determine, in writing delegate, whether in general, in a particular case or in cases of a particular nature, to any officer in the Department any power conferred upon her or him by or under these regulations.
- (2) The Director-General shall not be divested of a power delegated by her him under subregulation (1), and may alter or set aside any decision by an officer taken in the exercise of a power so delegated.

Savings and withdrawal

22. (1) Subject to the provisions of subregulation (2) and (3), the regulations promulgated under Government Notice No. R. 1182 of 20 June 1986, No. R. 1354 of 17 October 1997, hereinafter referred to as the "repealed regulations", are hereby repealed.
- (2) Anything done in terms of a provision of the repealed regulations, unless inconsistent with the provisions of these regulations, shall be deemed to have been done in terms of the corresponding provisions of these regulations. These regulations shall prevail in the event of a contradiction.
- (3) The name and other particulars of a medical practitioner which, immediately before these regulations come into operation, appeared in the register referred to in regulation 14(1) of the repealed regulations shall be deemed to be entered in terms of regulation 14(1)(c) of these regulations.
- (4) The register kept by the Director-General in terms of regulation 14(2) of the repealed regulations is incorporated into and constitutes part of the register kept by the Director-General in terms of regulation 14(1) of these regulations.

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MINISTER OF HEALTH
