

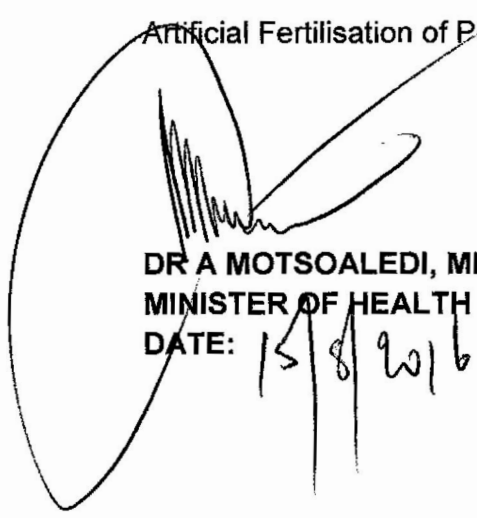
## DEPARTMENT OF HEALTH

NO. 1165

30 SEPTEMBER 2016

**NATIONAL HEALTH ACT, 2003 (ACT NO. 61 OF 2003)****REGULATIONS RELATING TO ARTIFICIAL FERTILISATION OF  
PERSONS**

I, Aaron Pakishe Motsoaledi, Minister of Health, hereby, after consultation with the National Health Council, in terms of Section 68(l) of the National Health Act, 2003 (No.61 of 2003), read with R.175 Regulations Relating to Artificial Fertilisation of Persons published on 02 March 2012 (Gazette No. 35099). Attached to this notice is the R.175 Regulations Relating to Artificial Fertilisation of Persons.



**DR A MOTSOALEDI, MP**  
**MINISTER OF HEALTH**  
**DATE:** 15/8/2016

**GOVERNMENT NOTICE****DEPARTMENT OF HEALTH****NATIONAL HEALTH ACT, 2003****REGULATIONS RELATING TO ARTIFICIAL FERTILISATION OF  
PERSONS**

The Minister of Health intends, under section 90(1) read with section 68(1)(l) of the National Health Act, 2003 (Act No. 61 of 2003) made regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed amendments to the Director-General: Health, Private Bag X 828, Pretoria, 0001, e-mail NetshP@health.gov.za (for the attention of Ms P Netshidzivhani), within three month from the date of this notice.

**SCHEDULE****Definitions**

1. In these Regulations any word or expression to which a meaning has been assigned in the Act have such meaning and, unless the context otherwise indicates –

**“artificial fertilisation”** means the introduction other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction and includes artificial insemination, *in vitro*

fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection;

**“artificial insemination”** means the placing of male gametes (sperm) into the fallopian tubes of the recipient;

**“cell”** means the basic structural and functional unit in people and all living things;

**“central data bank”** means an electronic database into which all information regarding use of individual donated gametes and artificial fertilisation treatment outcome is stored and managed;

**“competent person”** means a medical practitioner registered with the Health Professions of South Africa (HPCSA) with expertise in specialist gynaecologist and sub-specialist in Reproductive Medicine, or a trainee in Reproductive Medicine in a training unit under the supervision of a registered HPCSA sub-specialist;

**“database”** means a database contemplated in regulation 15(1);

**“deceased”** means a dead person in somatic death where there is cessation of circulation and respiration, including loss of corneal reflexes, the eyeballs become flaccid, and the pupils are fixed and dilated;

**“embryo transfer”** means the placing of the embryo into the uterus or fallopian tubes of the recipient;

**“freezing or cryopreservation”** means freezing or cryopreserving genetic material including ova, sperm, embryos, ovarian tissue or stem cells by an authorised institution;

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

**“genetic carrier”** means an individual who has a disease-causing mutation but will not develop the condition and the individual would have one normally functioning and one faulty gene (i.e. a heterozygote);

**“intracytoplasmic sperm injection”** is the process of microscopic technology to bring about fertilisation of an ovum with a male sperm outside the body in an authorised institution;

**“in vitro fertilisation”** is the process of spontaneous fertilisation of an ovum with a male sperm outside the body in an authorised institution;

**“oocyte”** means the female gamete;

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

**“sperm”** means the male gamete;

**“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; and

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

### **Application of the Regulations**

2. These regulations only apply to the withdrawal of gametes from and for use in living persons.

### **Application for authorisation**

3. (1) A competent person must apply for authorisation of a fertility clinic to the Director General indicating why authorisation is required.

(2) The Director-General must keep a database of authorised fertility clinics;

(3) The application referred to in sub regulation (1) must contain the following information:

- (a) the name and nature of the application;
- (b) location of the premises where business is to be conducted;
- (c) an indication of how records and data are kept;
- (d) the quality management system to be used;
- (e) details of the competent person; and
- (f) any other information the Director-General may consider necessary for the consideration of the application.

(4) The Director-General may, on application in terms of sub-regulation (1)-

- (a) cause the applicant to be investigated; or

- (b) obtain such further information as he or she deems necessary for the consideration of the application;
- (c) authorise the applicant concerned as a fertility clinic, subject to such conditions as he or she may determine; and
- (d) where such applicant is not approved, the Director General must notify the applicant in writing accordingly, stating the reason for such non-authorisation.

#### **Removal or withdrawal and storage of gametes**

4. (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 sub-regulation (1), they must be stored in a frozen state or cryopreserved.

#### **Compensation in respect of the withdrawal or removal of gametes**

5. 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**

6. The Director-General must establish an electronic central database into which all information regarding the use of individual donated gametes and artificial fertilisation treatment outcome are stored.

**Restriction on donation of gametes****7. (1) A competent person –**

- (a) may not remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of a gamete donor for a new recipient if the competent person has information or suspects that a maximum of 12 live births have been reached through the artificial fertilisation using the gametes of that gamete donor;
- (b) must, where the gamete donor has been used and resulted in 12 live births as contemplated in paragraph (a), inform that gamete donor that he or she may not make any further donation of gametes to a new recipient unless the provisions of sub-regulation (2) apply; 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 contemplated in regulation 6;

(2) Where the maximum number of 12 live births have been reached using the gametes of a specific donor, the Minister may allow a family to use the gametes from that donor to have an additional sibling.

(3) The competent person and the central data bank must ensure that gametes from a single donor are not used for more than 12 live births.

**Prerequisites for removal or withdrawal of gametes**

8. 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, must, 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 file, to which a unique identification number is allocated in respect of the gamete donor;
- (b) ensure that 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 not more than 12 live births have been reached 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 informed consent from the gamete donor relating to –
  - (i) physical examination and questioning by a competent person;
  - (ii) the removal or withdrawal a gamete for testing, analysing or other processing as the competent person may deem necessary;
  - (iii) particulars contemplated in regulation 9(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; and
  - (iv) to particulars contemplated in regulation 9(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;
- (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; and
- (j) must, in the event of a request in respect of which the donor and recipient are known to each other, ensure that there is-
  - (i) written confirmation by both parties that they know each other;
  - (ii) psychological evaluation of both parties.

**Gamete donor files, availability of information and destruction of gametes**

9. (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 8(i); and
    - (iv) subject to regulation 7(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 8(e);
  - (f) results of the tests and the analysis or examination contemplated in regulation 8(e) to (g); and
  - (g) any other relevant document or information that the competent person may request.
- (2) The competent person—
- (a) must retain the gamete donor file in safe-keeping and may not destroy the file, except with the written permission of the Director-General;
  - (b) must make the particulars set out in sub-regulation (1)(a)(ii), (iii) and (iv), (b),(c) and (f), together with the identification number referred to in regulation 8(a), available to the recipient and the competent person who is to effect the artificial fertilisation of the recipient;
  - (c) must furnish the central data bank 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 live births reached through the artificial fertilisation from the gametes of the specific gamete donor;
- (d) must 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) must immediately, after, if it has come to her or his attention that a maximum of 12 live births through the artificial fertilisation has been reached from the gametes of a specific gamete donor –
  - (i) make a conspicuous note to that effect in the gamete donor file;
  - (ii) make available this information to 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 for use as contemplated in regulation 7(2); and
  - (iv) inform the donor of the actions taken as in terms of sub-paragraph (iii).
- (f) who wants to keep the gametes referred to in sub-paragraph (iii) -
  - (i) must forthwith address the 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) must refrain from destroying the gametes until the Minister notifies the competent person of her or his decision.

**Place where and person who effects artificial fertilisation and embryo transfer**

**10.** (1) Artificial fertilisation or embryo transfer must only be effected at an authorised institution; and

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

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

**11.** (1) 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 8 (e) to (g), as the case may be, are not available yet; or
- (c) from the gamete donor younger than 18 years of age except in the case of a medical indication, may be used for artificial fertilisation.

- (2) (a) A competent person may not effect in vitro fertilisation 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) an embryo, referred to in paragraph (a) must be stored in a frozen/cryopreserved state in a prescribed institution;
- (c) a competent person may destroy an embryo, which she or he has in storage as soon as the recipient for whom that 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 embryo for a further period for the purpose of a subsequent embryo transfer to that recipient; or
- (ii) the recipient consents in writing that the competent person –
  - (aa) may, with the informed consent of such recipient, use such embryo for transfer to another specific recipient; or
  - (bb) may, with the informed consent of such recipient; use the embryo for a purpose, other than embryo transfer, which purpose must be stated in that consent,
- (d) a competent person may destroy an embryo that has been unclaimed by the recipient for a period of 10 years.

### **Requirements for artificial fertilisation and embryo transfer**

**12.** A competent person intending to effect the artificial fertilisation or embryo transfer to a recipient must, 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 is allocated in respect of the recipient;
- (b) obtain informed consent from the recipient relating to–
  - (i) physical examination and questioning by a competent person;
  - (ii) the removal or withdrawal of a gamete from the body of the donor for the purpose of such testing, analysing or

- other processing of that gamete, as the competent person may deem necessary;
- (iii) artificial fertilisation of, or embryo transfer to herself;
  - (iv) particulars contemplated in regulation 14(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 9(1)(a)(i) to (iv) are conformed with;
  - (ii) the recipient's particulars and wishes referred to in regulation 14(1)(a)(i) to (iii) are conformed with;
  - (iii) if the recipient or the gamete donor should 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 –
    - (aa) 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 artificial fertilisation ; 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.

- (2) 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 requiring the contrary.

### **Pre-implantation and prenatal testing for sex selection**

**13.** Pre-implantation and prenatal testing for selecting the sex of a child is prohibited except in the case of a serious sex linked or sex limited genetic conditions.

### **Recipient files and availability of information**

**14.** (1) A competent person who effects the artificial fertilisation of or embryo transfer to a recipient must immediately record or file the following particulars and documents in a recipient file referred to in regulation 12(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 infections, or communicable diseases in respect of the recipient;
  - (c) particulars of genetic evaluation made in respect of the recipient;
  - (d) particulars of an evaluation if indicated, made of the psychological or social suitability of the recipient with a view to her artificial fertilisation;
  - (e) the informed consent contemplated in regulation 12(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 of or embryo transfer –
    - (i) the number of embryos effected for the embryo transfer to the recipient;
    - (ii) the number of embryos used for each embryo transfer procedure;
    - (iii) the number of embryos in storage;
    - (iv) the number of embryos used for purposes other than embryo transfer; and
    - (v) the number of embryos destroyed.
- (2) The competent person referred to in sub-regulation (1) must –
- (a) retain the recipient file in safe-keeping and may 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) make available to the central data bank before 31 January of each year 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;
  - (iv) the particulars contemplated in sub-regulation (1)(g); and
  - (v) the results of each procedure referred to in subparagraph (ii).

**Recording of names of authorised institutions and competent persons in the database**

**15.** (1) The Director-General must keep an electronic database with particulars of –

- (a) authorised institutions 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.

(2) The Director-General must delete from the database 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 database;
- (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 Director-General to remove the name of such a place from the database.

(3) A competent person who has changed her or his name or address of practice or a person in charge of an authorised or prescribed institution, the name or address of which has been changed, must within 30 days of such change inform the Director-General in writing of such change.

(4) The Director-General 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 contemplated 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; or
- (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 database, and must in writing notify the person in

charge of such authorised or prescribed institution accordingly.

(5) Any notice referred to in sub-regulation (4) must provide sufficient details of grounds for the deletion.

(6) The deletion made in terms of this regulation must-

- (a) be entered in the database; and
- (b) be valid until the danger or situation which gave rise to such provisional deletion has, to the satisfaction of the Director-General 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 database and may not perform artificial fertilisation or embryo transfer.

### **CHAPTER 3**

#### **GENERAL SUPPLEMENTARY PROVISIONS**

##### **Reporting of births**

- 16.** (1) (a) All births delivered as a result of artificial fertilisation must be recorded by the person in charge of the facility where such delivery has taken place, into the central data bank within three months of such birth.
- (b) The mother who gives birth must 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 sub-regulation (1) must include, but not limited to:
- (a) confirmation 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**

**17.** (1) An authorised institution that effected the artificial fertilisation or embryo transfer must, 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) must, 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**

**18.** (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 the recipient.

### **Prohibition of Disclosure of certain facts**

**19.** No person may 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 except where a law provides otherwise or a court so orders.

### **Appeals**

- 20.** (1) (a) A person aggrieved by the decision of the Director-General in terms of these regulations may within 14 days of receiving such decision, appeal in writing to the Minister against such decision.

- (b) A copy of the appeal must be sent to the Director-General for his or her information and response if necessary.
- (2) An appeal in terms of sub-regulation (1) must clearly state the grounds on which such appeal is lodged.
- (3) The Minister may confirm, amend or revoke a decision taken by the Director-General in terms of the provisions of these regulations and thereafter inform the appellant of her or his decision.

### **Offences and penalties**

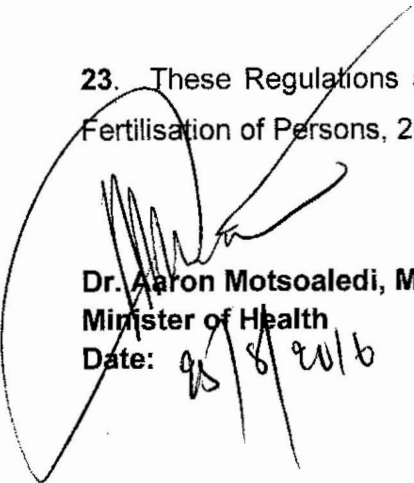
21. Any person who contravenes or fails to comply with any provision of these regulations commits an offence and is liable on conviction to a fine or imprisonment for a period not exceeding 10 years, or to both such fine and imprisonment.

### **Repeal**

22. The Regulations Relating to Artificial Fertilisation of Persons, 2012, published in Government Notice No. R175, Government Gazette No. 35099 dated 2 March 2012 are hereby repealed.

### **Short Title**

23. These Regulations are called Regulations Relating to Artificial Fertilisation of Persons, 2016.



**Dr. Aaron Motsoaledi, MP**  
**Minister of Health**  
Date: 28/8/2016