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Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA)

of 18 December 1998 (Status as of 1 January 2013)

The Federal Assembly of the Swiss Confederation,
on the basis of Articles 24^{novies} paragraphs 1 and 2, 64 and 64^{bis}
of the Federal Constitution¹,
and having considered the Dispatch of the Federal Council dated 26 June 1996²,
decrees:

Chapter 1: General Provisions

Art. 1 Subject and purpose

¹ This Act specifies the conditions under which the techniques of medically assisted reproduction may be used in humans.

² It protects human dignity, personality and the family and prohibits misuses of biotechnology and gene technology.

³ It provides for the establishment of a national ethics commission.

Art. 2 Definitions

In this Act:

- a. *techniques of medically assisted reproduction (assisted reproductive techniques)* means methods of establishing a pregnancy without sexual intercourse – in particular, insemination, *in vitro* fertilisation with embryo transfer and gamete transfer;
- b. *insemination* means the introduction, by means of instruments, of sperm cells into the female reproductive organs;
- c. *in vitro fertilisation* means the bringing together of an ovum and sperm cells outside the woman's body;

AS 2000 3068

¹ [BS 1 3; AS 1992 1579]. Articles 119, 122 and 123 of the Federal Constitution of 18 April 1999 (SR 101) now correspond to these provisions.

² BBl 1996 III 205

- d. *gamete transfer* means the introduction, by means of instruments, of sperm cells and ova into the uterus or a Fallopian tube;
- e. *reproductive cells (gametes)* means sperm cells and ova;
- f. *germline cells* means reproductive cells (including their precursor cells), impregnated ova and embryonic cells whose genetic material can be passed on to offspring;
- g. *impregnation* means causing a sperm cell to penetrate into the cytoplasm of an ovum, in particular by insemination, gamete transfer or *in vitro* fertilisation;
- h. *impregnated ovum* means the fertilised ovum before pronuclear fusion;
- i. *embryo* means the developing offspring from the time of pronuclear fusion until the end of organogenesis;
- j. *foetus* means the developing offspring from the end of organogenesis until birth;
- k. *surrogate mother* means a woman who is prepared to become pregnant by means of an assisted reproductive technique, to carry the foetus to term and to surrender the child permanently to third parties after delivery;
- l. *cloning* means the artificial production of genetically identical organisms;
- m. *chimera formation* means the fusion of totipotent cells from two or more genetically different embryos. Embryonic cells are totipotent if they are capable of developing into any type of specialised cell;
- n. *hybrid formation* means causing a non-human sperm cell to penetrate into a human ovum, or a human sperm cell into a non-human ovum.

Chapter 2: Techniques of Medically Assisted Reproduction

Section 1: Principles

Art. 3 Well-being of the child

¹ Assisted reproductive techniques may be used only if the well-being of the child is ensured.

² They may only be used in couples:

- a. where a basis for a parent-child relationship exists in accordance with Articles 252–263 of the Swiss Civil Code³ (CC) and
- b.⁴ who, on the basis of their age and personal circumstances, are likely to be able to care for and bring up the child until it reaches the age of majority.

³ Only married couples may use donated sperm cells.

³ SR 210

⁴ Amended by Annex No 20 of the Federal Act of 19 Dec. 2008 (Adult Protection, Law of Persons and Law of Children), in force since 1 Jan. 2013 (AS 2011 725; BBl 2006 7001).

⁴ Reproductive cells or impregnated ova may not be used after the death of the person from whom they were obtained.

Art. 4 Prohibited practices

Ovum and embryo donation and surrogate motherhood are prohibited.

Art. 5 Indications

¹ Assisted reproductive techniques may be used only if:

- a. the aim is to enable a couple to overcome infertility and other treatment methods have failed or offer no prospect of success; or
- b. there is no other way of avoiding the risk of transmitting a serious, incurable disease to the offspring.

² Without prejudice to Article 22 paragraph 4, reproductive cells may be selected so as to influence the sex or other characteristics of the future child only if there is no other way of avoiding the risk of transmitting a serious, incurable disease to the offspring.

³ The removal and analysis of one or more cells from an embryo *in vitro* are prohibited.

Art. 6 Information and counselling

¹ Before an assisted reproductive technique is used, the physician must carefully inform the couple about:

- a. the various causes of infertility;
- b. the medical procedure, including the prospects of success and the risks involved;
- c. the risk of a multiple pregnancy;
- d. possible psychological and physical stresses; and
- e. the legal and financial aspects.

² In the counselling session, appropriate reference should also be made to alternative ways of living and other family-building options.

³ There must be an appropriate period for reflection, generally lasting four weeks, between the counselling session and treatment. It must be pointed out that the couple may also seek independent advice.

⁴ Psychological support must be offered before, during and after treatment.

Art. 7 The couple's consent

¹ Assisted reproductive techniques may be used only with the written consent of the couple concerned. After three unsuccessful treatment cycles, renewed consent and a further period for reflection are required.

² The written consent of the couple is also required for the reactivation of impregnated ova.

³ If an assisted reproductive technique involves an increased risk of multiple pregnancy, the procedure may be carried out only if the couple are prepared to accept a multiple birth.

Section 2: Licensing requirements

Art. 8 Principle

¹ A cantonal licence is required by Any person who:

- a. uses assisted reproductive techniques;
- b. receives reproductive cells or impregnated ova for preservation or arranges the supply of donated sperm cells without personally using assisted reproductive techniques.

² No licence is required for insemination using a partner's sperm cells.

Art. 9 Use of assisted reproductive techniques

¹ A licence for the use of assisted reproductive techniques shall only be granted to physicians.

² They must:

- a. have the necessary training and experience in the methods of medically assisted reproduction;
- b. ensure that such activities are carried out with due care and in compliance with the law;
- c. together with staff, ensure that the persons to be treated receive comprehensive counselling and support with regard to the medical, reproductive biological and socio-psychological aspects of the procedure;
- d. have the necessary laboratory equipment;
- e. ensure that the reproductive cells and impregnated ova are preserved in accordance with the current state of science and practice.

³ Comprehensive genetic counselling must be provided to couples if assisted reproductive techniques are used to avoid the transmission of a serious, incurable disease.

Art. 10 Preservation and supply of reproductive cells and impregnated ova

¹ A licence for the preservation of reproductive cells and impregnated ova or for the supply of donated sperm cells shall only be granted to physicians.

² They must:

- a. ensure that such activities are carried out with due care and in compliance with the law;

- b. together with staff, ensure that sperm donors are carefully selected; and
- c. ensure that reproductive cells and impregnated ova are preserved in accordance with the current state of science and practice.

Art. 11 Reporting

¹ Licence holders must submit an annual report on their activities to the licensing authority.

² The report must provide information on:

- a. the number and type of treatments;
- b. the type of indications;
- c. the use of donated sperm cells;
- d. the number of pregnancies and their outcome;
- e. the preservation and use of reproductive cells and impregnated ova;
- f. the number of surplus embryos.

³ It must not contain any information revealing the identity of specific people.

⁴ The licensing authority shall transmit the data to the Federal Statistical Office for evaluation and publication.

Art. 12 Supervision

¹ The licensing authority shall ensure that the requirements for the granting of a licence continue to be met and that any conditions stipulated are fulfilled.

² It shall carry out unannounced inspections.

³ If any serious infringements of this Act are determined, it shall withdraw the licence.

Art. 13⁵**Art. 14** Implementing provisions

The Federal Council shall enact the implementing provisions concerning the granting and withdrawal of licences, and reporting and supervision.

⁵ Repealed by Annex No 87 of the Federal Act on the Federal Administrative Court of 17 June 2005, in force since 1 Jan. 2007 (SR 173.32).

Section 3: Handling of Reproductive Material**Art. 15** Preservation of reproductive cells

¹ Reproductive cells may be preserved only with the written consent of the person from whom they were obtained, and for a maximum of five years.

² A longer preservation period may be agreed with persons who have their reproductive cells preserved with a view to producing their own offspring at a later date because medical treatment they undergo or an activity they carry out could lead to infertility or damage to their genetic material.

³ The person from whom the reproductive cells are obtained may, at any time, in writing, revoke consent to their preservation and use.

⁴ If consent is revoked or the preservation period expires, then the reproductive cells are to be destroyed immediately.

Art. 16 Preservation of impregnated ova

¹ Impregnated ova may only be preserved if:

- a. the couple to be treated give their written consent; and
- b. preservation is intended to permit subsequent establishment of a pregnancy.

² The maximum preservation period shall be five years.

³ Either partner may revoke his or her consent at any time in writing.

⁴ If consent is revoked or the preservation period expires, then the impregnated ova are to be destroyed immediately.

⁵ The Federal Council shall prohibit the preservation of impregnated ova if the current state of science and practice allows non-impregnated ova to be preserved with satisfactory results.

Art. 17 Development of embryos

¹ The number of impregnated ova developed into embryos outside the woman's body must not be greater than is required to establish a pregnancy within one cycle; the maximum number shall be three.

² The embryo may only be developed outside the woman's body to the extent that is essential in order to permit implantation in the uterus.

³ The preservation of embryos is prohibited.

Section 4: Sperm Donation**Art. 18** The donor's informed consent

¹ Donated sperm cells may only be used in legitimate assisted reproductive techniques and for purposes to which the donor has given his written consent.

² Before donating sperm, the donor must be informed in writing about the legal situation, and in particular the right of the child to obtain information on the donor's records (Article 27).

Art. 19 Selection of donors

¹ Donors must be carefully selected according to medical criteria; in particular, health risks for the recipient of the donated sperm cells must be excluded as far as possible. Other selection criteria are prohibited.

² The donor may provide his sperm cells to only one centre; he must be expressly informed of this restriction prior to donation.

Art. 20 Supply of donated sperm cells

¹ Donated sperm cells may only be supplied to persons who have a licence to use assisted reproductive techniques; the data specified in Article 24 paragraph 2 is also to be provided.

² Any person who receives donated sperm cells must ensure compliance with Article 22 paragraph 2.

Art. 21 Non-remuneration

No payment shall be made for sperm donation as such.

Art. 22 Use of donated sperm cells

¹ Sperm cells from different donors must not be used within one cycle.

² Sperm cells from one donor may be used to produce a maximum of eight children.

³ When an assisted reproductive technique is used, the relationship between the persons from whom the reproductive cells are obtained must not constitute an impediment to marriage in accordance with Article 95 of the Swiss Civil Code⁶.

⁴ When donated sperm cells are selected, only the donor's blood group and similarity in physical appearance to the man with whom filiation is to be established shall be taken into account.

Art. 23 Filiation

¹ A child conceived through sperm donation in accordance with the provisions of this Act cannot contest filiation with the husband of his or her mother. An action contesting paternity by the husband is subject to the provisions of the Swiss Civil Code (CC)⁷.

² If a child has been conceived through sperm donation, a paternity action against the sperm donor (Article 261 ff. CC) is not permitted; however, such an action is

⁶ SR 210

⁷ SR 210

permissible if the donor knowingly donated sperm at the place of a person who was not licensed to use assisted reproductive techniques or to preserve and supply donated sperm cells.

Art. 24 Documentation requirements

¹ Any person who receives or uses donated sperm cells must document the donation in a reliable manner.

² In particular, the following data about the donor is to be recorded:

- a. family name and first name, date and place of birth, place of residence, place of origin in Switzerland or nationality, occupation and education;
- b. date of the sperm donation;
- c. results of the medical examination;
- d. information about physical appearance.

³ Concerning the woman for whom the donated sperm cells are used and her husband, the following data is to be recorded:

- a. family name and first name, date and place of birth, place of residence, place of origin in Switzerland or nationality;
- b. date on which the sperm cells are used.

Art. 25 Transmission of data

¹ Immediately after the birth of the child, the physician who carried out the reproductive procedure must transmit the data specified in Article 24 to the Federal Civil Status Office (Federal Office).

² If the physician has not been informed of a birth, then he or she must transmit the data immediately after the calculated date of birth, unless it has been established that the treatment was unsuccessful.

³ The Federal Council shall enact the necessary provisions on data protection.

Art. 26 Retention of data

The Federal Office shall retain the data for 80 years.

Art. 27 Information

¹ Once the child has reached 18 years of age, he or she may request information from the Federal Office about the donor's physical appearance and personal data (Art. 24 para. 2 lets. a and d).

² In addition, the child may at any time request information on all the data relating to the donor (Art. 24 para. 2) if he or she has a legitimate interest in obtaining it.

³ Before the Federal Office discloses personal data, it shall inform the donor if possible. If the donor does not wish to have personal contact, then the child must be

informed and made aware of the donor's rights of privacy and his family's entitlement to protection. If the child insists on his or her right to obtain information under paragraph 1, the information shall be provided.

⁴ The Federal Council may assign responsibility for handling requests for information to a specialised federal commission.

⁵ ...⁸

Chapter 3: National Ethics Commission

Art. 28

¹ The Federal Council shall establish a national ethics commission.

² The commission shall monitor developments in assisted reproductive techniques and gene technology in the area of human medicine and comment from an ethical perspective, in an advisory capacity, on associated social, scientific and legal issues.

³ In particular, the commission shall have the following tasks:

- a. to draw up additional guidelines relating to this Act;
- b. to identify gaps in the legislation;
- c. to advise the Federal Assembly, the Federal Council and the cantons on request;
- d. to inform the public about important findings and to promote debate on ethical matters within society.

The Federal Council shall determine the other tasks to be carried out by the commission in the area of human medicine. It shall enact implementing provisions.

Chapter 4: Criminal Provisions⁹

Art. 29 Production of embryos for illegitimate purposes

¹ Any person who produces an embryo by impregnation with the intention of using it or having it used for purposes other than the establishment of a pregnancy shall be liable to a term of imprisonment.

² The same penalty shall apply to any person who preserves an impregnated ovum with the intention of using it or having it used for purposes other than the establishment of a pregnancy.

⁸ Repealed by Annex No 87 of the Federal Act on the Federal Administrative Court of 17 June 2005, in force since 1 Jan. 2007 (SR 173.32).

⁹ From 1 Jan. 2007 the penalties stipulated are to be interpreted, and the limitation periods converted, in accordance with Article 333 paragraphs 2–6 of the Criminal Code (SR 311.0) in the amended version of 13 Dec. 2002 (AS 2006 3459).

Art. 30 Development of embryos outside the woman's body

¹ Any person who allows an embryo to develop outside the woman's body beyond the point at which implantation in the uterus remains possible shall be liable to a term of imprisonment.

² The same penalty shall apply to Any person who transfers a human embryo to an animal.

Art. 31 Surrogate motherhood

¹ Any person who uses an assisted reproductive technique in a surrogate mother shall be liable to a term of imprisonment or to a fine.

² The same penalty shall apply to any person who acts as an intermediary for surrogate motherhood.

Art. 32 Misuse of reproductive material

¹ Any person who uses reproductive material obtained from an embryo or foetus to bring about impregnation or further development into an embryo shall be liable to a term of imprisonment.

² Any person who purchases or sells human reproductive material or products derived from embryos or foetuses shall be liable to a term of imprisonment or to a fine.

³ If the offender acts in a professional capacity, the penalty shall be a term of imprisonment and a fine of up to 100,000 francs.

Art. 33 Impermissible selection of reproductive cells

Any person who, when using an assisted reproductive technique, selects reproductive cells by sex or on the basis of a genetic analysis, without thereby intending to avoid the transmission of a serious, incurable disease to the offspring, shall be liable to a term of imprisonment or to a fine.

Art. 34 Acting without consent or a licence

¹ Any person who uses an assisted reproductive technique without the consent of the person from whom the reproductive cells are obtained or of the couple being treated shall be liable to a term of imprisonment or to a fine.

² The same penalty shall apply to any person who, acting without a licence or having obtained a licence by fraudulent means, uses assisted reproductive techniques or preserves or supplies reproductive cells or impregnated ova.

Art. 35 Germ-line modifications

¹ Any person who genetically modifies a germline cell or an embryonic cell shall be liable to a term of imprisonment.

² The same penalty shall apply to any person who uses a genetically modified reproductive cell for impregnation or uses a similarly modified impregnated ovum for further development into an embryo.

³ Paragraph 1 does not apply if the modification of germline cells is an unavoidable concomitant effect of chemotherapy, radiotherapy or another medical treatment that a person is undergoing.

Art. 36 Cloning, chimera and hybrid formation

¹ Any person who creates a clone, a chimera or a hybrid shall be liable to a term of imprisonment.

² The same penalty shall apply to any person who transfers a chimera or a hybrid to a woman or to an animal.

Art. 37 Contraventions

Any person who wilfully:

- a. uses an assisted reproductive technique in a woman in contravention of Article 3 paragraph 2 letter a and paragraph 3;
- b. uses reproductive cells or impregnated ova obtained from a person who has died;
- c. uses donated ova, develops an embryo using donated ova and donated sperm cells, or transfers a donated embryo to a woman;
- d. uses assisted reproductive techniques in the absence of a permissible indication;
- e. removes and analyses cells in contravention of Article 5 paragraph 3;
- f. preserves reproductive material in contravention of Articles 15, 16 and 42;
- g. develops embryos in contravention of Article 17 paragraph 1;
- h. donates sperm cells to several holders of licences under Article 8 paragraph 1;
- i. uses donated sperm cells in contravention of Article 22 paragraphs 1–3;
- j. incorrectly or incompletely records data required in accordance with Article 24

shall be liable to a term of imprisonment or to a fine of up to 100,000 francs.

Art. 38 Competent authority

The prosecution and adjudication of offences under this Act is the responsibility of the cantons.

Chapter 5: Final Provisions

Section 1: Amendment of Current Legislation

Art. 39

...¹⁰

Section 2: Transitional Provisions

Art. 40 Licensing

¹ Any person who requires a licence according to Article 8 paragraph 1 must submit an application, together with the required documents, to the licensing authority within three months after the commencement of this Act.

² Any person who does not submit the application within the specified period must discontinue the activities concerned.

Art. 41 Information

¹ Articles 18 and 24–27 also apply if sperm cells have been donated before, but are only used after, the commencement of this Act.

² In all other cases, physicians who have used assisted reproductive techniques using donated reproductive cells must provide information, with the provisions of Article 27 applying *mutatis mutandis*.

Art. 42 Storage of embryos

¹ Any person who is storing embryos when this Act commences must inform the licensing authority accordingly within three months. Article 11 applies.

² The embryos may be stored for purposes of reproduction until 31 December 2005 at the latest. If embryos are no longer used for this purpose or if this deadline expires, then, with the written informed consent of the couple concerned, they may be stored for research purposes until 31 December 2008, and, when the relevant legislation comes into force, used in accordance with the provisions thereof. The couple concerned may call for their consent to be requested once again before an embryo is used for research purposes.¹¹

Art. 43 Filiation

Article 23 also applies to children conceived before the commencement of this Act by means of an assisted reproductive technique using donor sperm.

¹⁰ The amendment may be consulted under AS 2000 3055.

¹¹ Amended by No I of the Amendment of 3 Oct. 2003, in force until 31 Dec. 2008 (AS 2003 3681; BBl 2003 1163).

Section 3: Referendum and Commencement

Art. 44

¹ This Act is subject to an optional referendum.

² The Federal Council shall determine the commencement date.

Commencement date: 1 January 2001¹²

¹² Federal Council Decree of 4 Dec. 2000 (AS 2000 3067)

