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Reproductive Medicine Ordinance
(RMO)

of 4 December 2000 (Status as of 1 January 2019)

The Swiss Federal Council,

based on Articles 14 and 25 paragraph 3 of the Reproductive Medicine Act of 18 December 1998[1] (the Act),

ordains:

Chapter 1 Licensing

Section 1 Subject Matter

Art. 1[2]

A licence as specified in Article 8 paragraph 1 of the Act is required by any person who, as holder of a cantonal professional practising licence, independently or as a team leader:

a. uses assisted reproductive techniques;

b. receives reproductive cells, impregnated ova or embryos *in vitro* for preservation or arranges the supply of donated sperm cells without personally using assisted reproductive techniques.

Section 2 Licence Requirements

Art. 2[3] Evidence of qualifications for the use of assisted reproductive techniques

[1] Any person who uses assisted reproductive techniques requires:

a. the Swiss obstetrics and gynaecology specialist title with the gynaecological endocrinology and reproductive medicine specialty or an equivalent recognised foreign specialist title; and

AS **2000** 3068

1 SR **810.11**

2 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).

3 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).

b. the cantonal licence to practise as an independent professional.

2 Any person who limits the activity to insemination with sperm cells from a third party requires:

a. the Swiss obstetrics and gynaecology specialist title or an equivalent recognised foreign specialist title; and

b. the cantonal licence to practise as an independent professional.

Art. 3[4] Evidence of qualifications to preserve and supply reproductive material

Any person who receives reproductive cells, impregnated ova or embryos *in vitro* for preservation or arranges the supply of donated sperm cells without personally using assisted reproductive techniques requires:

a. a Swiss or a recognised foreign medical specialist title; and

b. the cantonal licence to practise as an independent professional.

Art. 4[5] Reproductive medicine laboratory

1 Any person who uses reproductive techniques requires a reproductive medicine laboratory that meets the following requirements:

a. It is managed by a person who:

1. has completed a university course of studies in accordance with the Medical Professions Act of 23 June 2006[6] or a masters in the field of biology or chemistry from a tier-one university accredited under the Higher Education Act of 30 September 2011[7] or a state-recognised or accredited foreign tier-one university;

2. has received postgraduate training that the supervisory authority regards as suitable; and

3. is familiar with the current state of the art as a result of receiving suitable continuing professional training.

b. The staff have the required professional skills and qualifications.

c. The laboratory operates a quality management system that is commensurate with the procedures offered and which is based on the standards specified in Annex 2.

2 The Federal Department of Home Affairs may update Annex 2 in line with international or technical developments. In consultation with the Federal Department of Economic Affairs, Education and Research, it shall make updates that may have the effect of being technical barriers to trade.

4 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
5 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
6 SR **811.11**
7 SR **414.20**

Art. 5 Use of donated sperm cells

1 Any person wishing to use assisted reproductive techniques using donated sperm cells must indicate in the application:

a. how donors are to be recruited and informed about the legal situation (Art. 18 para. 2 of the Act);

b. how health risks for the recipient are to be avoided.

2 Any person wishing to supply donated sperm cells must indicate:

a. what charge will be made to defray expenses;

b. how it will be ensured that data is duly recorded in accordance with Article 24 of the Act and Article 17 of this Ordinance.

3 Any changes are to be notified to the supervisory authority.

Art. 6[8] Counselling and care

1 Together with the application for a licence to use assisted reproductive techniques, plans must submitted for the provision of social psychological counselling and support, as specified in Article 9 paragraph 2 letter c of the Act.

2 Where it is planned to use reproductive techniques with an analysis of the genetic material of reproductive cells or embryos *in vitro* or with the selection of donor sperm cells to prevent the transmission of a serious illness, a proposal with regard to genetic counselling in accordance with Article 6*a* of the Act must be submitted.

Art. 7 Information on scientific staff

1 The personal data and training certificates of scientific staff must be enclosed with the application for a licence.

2 Any changes are to be notified. The supervisory authority may provide for exceptions in the licence.

Section 3 Licensing and Supervision

Art. 8 Responsibility

1 The body responsible for licensing and supervision shall be the department responsible for healthcare in the canton where the activity specified in Article 8 paragraph 1 of the Act is carried out.

2 The cantons may designate another authority which has the necessary expertise.

8 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).

Art. 9 Licensing

[1] The licence to use assisted reproductive techniques may be restricted to certain techniques.

[2] The licence may be granted for a limited term and subject to conditions.

[3] …[9]

Art. 10[10] Supervision

[1] Within a year of granting a licence, the supervisory authority shall arrange for an inspection to be carried out by an expert. Thereafter, an inspection shall be carried out as often as necessary, but at least once every three years.

[2] The supervisory authority may consult an independent expert.

[3] Persons charged with carrying out an inspection shall be granted access at all times to the premises and facilities used to perform the activities concerned.

[3] If the laboratory is accredited under the Accreditation and Designation Ordinance of 17 June 1996[11], the supervisory authority may dispense with all or part of the review of the quality management system.

[4] The Swiss Accreditation Service shall notify the supervisory authority within an appropriate period of accreditations that have been granted or renewed as well as of any that have been suspended or revoked.

Art. 11 and **12**[12]

Art. 13 Expiry

The licence shall expire when the licensed activities are discontinued. Discontinuation of activities is to be notified to the supervisory authority.

Art. 14 Reporting

[1] Licence holders must submit an annual report on their activities, as specified in Article 11 of the Act, to the supervisory authority by no later than 1 May of the following year.

[2] The supervisory authority shall transmit the anonymised data to the Federal Statistical Office by no later than 1 July of the year in question for evaluation and publication. The data must not include any indication of the centres of reproductive medicine.

9 Repealed by No I of the O of 21 June 2017, with effect from 1 Sept. 2017 (AS **2017** 3651).
10 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
11 SR **946.512**
12 Repealed by No I of the O of 21 June 2017, with effect from 1 Sept. 2017 (AS **2017** 3651).

3 The Federal Statistical Office shall provide the supervisory authorities with a form for standardised data collection. This may also be used for the annual report on activities referred to in paragraph 1.

Art. 14*a*[13] Evaluation

The supervisory authority shall on request send the Federal Office of Public Health the data required for the evaluation in accordance with Article 14*a* paragraph 2 letter c of the Act together with the contact details for licence holders in accordance with Article 8 paragraph 1 of the Act.

Chapter 2 Data on Biological Origins

Section 1 Donor Data Register[14]

Art. 15[15] Competent authority

1 The Federal Civil Status Office (Federal Office) shall keep a register for storing the sperm donor data specified in Article 24 of the Act (donor data register).

2 The Federal Office shall issue processing regulations governing the establishment and management of the donor data register, and defining in particular the structure, procedures and access rights.

Art. 15*a*[16] Online management

1 The donor data register is kept electronically.

2 The transmitted data are stored in electronic form.

3 The electronic system for the management of the register and for storing the data must meet the following requirements:

a. the long-term existence and quality of the data are guaranteed.

b. the data are secured in accordance with recognised standards and the current state of the art;

c. the programming and the file format for the data are documented.

Art. 15*b*[17] Structure of the donor data register

1 The register contains a directory of the sperm donors.

2 Each sperm donor file contains the following information:

13 Inserted by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
14 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
15 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
16 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
17 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).