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Reproductive Medicine Ordinance (RMO)

of 4 December 2000 (Status as of 1 September 2023)

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

Any person who uses assisted reproductive techniques requires:

a. a Swiss obstetrics and gynaecology specialist title or a corresponding recognised foreign specialist title;

b. the qualifications to use the techniques according to the state of the art; 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).

c. the cantonal licence to practise as an independent professional.[4]

[1bis] It may be assumed that a person has the qualifications specified in paragraph 1 letter b if he or she meets the requirements of Annex 3.[5]

[1ter] The Federal Department of Home Affairs may amend Annex 3 if amendments to the professional requirements for the use of assisted reproductive techniques so require.[6]

[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

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

Art. 3[7] 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

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

Art. 4[8] 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[9] 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[10] 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.

4 Amended by Annex 6 No II 2 of the O of 23 Sept. 2022 on Human Genetic Testing, in force since 1 Dec. 2022 (AS **2022** 585).
5 Inserted by Annex 6 No II 2 of the O of 23 Sept. 2022 on Human Genetic Testing, in force since 1 Dec. 2022 (AS **2022** 585).
6 Inserted by Annex 6 No II 2 of the O of 23 Sept. 2022 on Human Genetic Testing, in force since 1 Dec. 2022 (AS **2022** 585).
7 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
8 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
9 SR **811.11**
10 SR **414.20**

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.

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[11] 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.

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

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.

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 ...[12]

Art. 10[13] 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[14], 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[15]

Art. 13 Expiry

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

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

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.

[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*[16] 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[17]

Art. 15[18] 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*[19] 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;

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

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

Art. 15*b*[20] 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:

a. the data transmitted by the attending doctor with the registration form for the sperm donor data (Art. 16 para. 1);

b. the results of the medical examinations (Art. 16 para. 1);

c. other donor data stored at the request of the sperm donor (Art. 17).

Art. 16[21] Transmission of the data to the Federal Office

[1] The data are transmitted by the attending doctor to the Federal Office in accordance with Articles 24 and 25 of the Act at the same time as the report of the sperm donor data; the form may be transmitted on paper (Art. 16*a*) or electronically (Art. 16*b*); the Federal Office issues the form.

[2] The other data may be transmitted at a time later than that specified in paragraph 1.

[3] The registration form for sperm donor data contains the following data:

a. relating to the donor:
   1. name and first name, date of birth and place of birth, place of residence, place of origin or nationality, occupation and education,
   2. date of the sperm donation,
   3. results of the medical examinations,
   4. description of the physical appearance: stature, size, hair colour, eye colour, skin colour, special features;

b. relating to the recipient of the sperm donation and her husband or her wife:[22]
   1. name and first name, date of birth and place of birth, place of residence, place of origin or nationality,
   2. date of the insemination or the embryo transfer;

c. relating to the child, if known by the attending doctor: name and first name, date of birth and place of birth, sex, place of residence; if details of the birth are not known: the probable date of birth;

d. relating to the doctor who stored or arranged the sperm donation, where this doctor is not the attending doctor: name and address.

20 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
21 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2012 (AS **2012** 6097).
22 Amended by No II of the O of 30 March 2022, in force since 1 July 2022 (AS **2022** 243).

Art. 16*a*[23] Transmission in paper form

[1] If the form is completed by hand, it must be completed legibly in block capitals and signed.

[2] If the form is illegible, incomplete, not signed or defective in some other way, the Federal Office may return it to the doctor, giving notice that he or she will be in breach of the obligation under Article 25 of the Act to transmit the data if the noted defects are not rectified.

[3] Data may be transmitted in accordance with Article 24 of the Act and Article 17 of this Ordinance by registered post or by private courier.

Art. 16*b*[24] Transmission in electronic form

[1] The Federal Office may request doctors who wish to transmit the data electronically that they register with a recognised platform for the secure service in accordance with Article 2 the Ordinance of 18 June 2010[25] on Electronic Service in Civil and Criminal Proceedings and Debt Enforcement and Bankruptcy Procedures.

[2] The doctors shall use the electronic form provided by the Federal Office on its website, on the secure service platform or by post.

[3] The form must bear a qualified electronic signature in accordance with Article 2 of the Federal Act of 18 March 2016[26] on Electronic Signatures.[27]

[4] A certified electronic signature is not required if identification of the sender and the integrity of the transmission is guaranteed in some other suitable way.

[5] The result of the medical examinations is transmitted to the Federal Office in PDF/A format.

[6] The doctors shall send documents that are not electronically transmitted by registered post or by private courier to the Federal Office.

[7] The electronic files shall be transmitted to the electronic postal address of the Federal Office and encrypted using its public key.

[8] Registration with the secure service platform is deemed to be consent to the Federal Office serving documents electronically. Consent may be revoked at any time.

[9] The principles relating to the detection and rectification of defects in forms transmitted on paper (Art. 16*a* para. 2) apply *mutatis mutandis*.

Art. 17 Storage of additional donor data

At the request of the sperm donor, additional donor data, in particular photographs of the donor, shall be stored as well as the data specified in Article 24 of the Act.

23 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2012 (AS **2012** 6097).
24 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
25 SR **272.1**
26 SR **943.03**
27 Amended by Annex No II 8 of the O of 23 Nov. 2016 on Electronic Signatures, in force since 1 Jan. 2017 (AS **2016** 4667).

Art. 18[28] Updating of stored data

At the request of the treated couple, the data held in the donor data register shall be updated. The couple shall provide the information required for this purpose.

Art. 19[29] Security of stored data

[1] The Federal Office shall ensure that the data in the donor data register and the data in accordance with Article 15*b* paragraph 2 are securely stored in accordance with the principles of data protection legislation.

[2] In particular, it shall ensure protection against fire, water, theft and unauthorised processing of the data.

Art. 19*a*[30] Electronic data carriers

[1] The files transmitted in paper form shall be digitalised and stored in electronic form. Following digitalisation, the paper copies shall be destroyed.

[2] The Federal Office may delegate these duties to an external agency, which undertakes in terms of a written agreement to record all the data electronically, treat it as confidential and guarantee its security. Article 9 of the Data Protection Act of 25 September 2020[31] applies *mutatis mutandis*.[32]

[3] The Federal Office shall confirm on request that the digitalised documents correspond to their originals in paper form

Art. 20[33] Archiving and destruction of the data

[1] On expiry of the retention period of 80 years (Art. 26 of the Act), the data in the donor data register and the data under Article 15*b* paragraph 2 shall be offered to the Federal Archives for archiving.

[2] The data regarded by the Federal Archives as not worthy of archiving shall be destroyed.

Section 2 Procedure for Disclosure of Information

Art. 21 Request for information

[1] The child must submit to the Federal Office a written request for information in accordance with Article 27 paragraph 1 or 2, specifying the mother's personal data.

28 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
29 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
30 Inserted by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2013 (AS **2012** 6097).
31 SR **235.1**
32 Second sentence amended by Annex 2 No II 90 of the Data Protection Ordinance of 31 Aug. 2022, in force since 1 Sept. 2023 (AS **2022** 568).
33 Amended by No I of the O of 31 Oct. 2012, in force since 1 Jan. 2012 (AS **2012** 6097).

2 The child must provide evidence of his or her identity in the form of a copy of a passport, identity card or an equivalent identity document and demonstrate that the requirements specified in Article 27 paragraph 1 or 2 of the Act are met.[34]

3 If the child is evidently incapable of acting on his or her own behalf, the Federal Office may request him or her to enlist a representative.[35]

Art. 22 Notification of the sperm donor

1 If the child fulfils the requirements specified in Article 27 paragraph 1 or 2 of the Act and requests information on the personal data of the sperm donor, the Federal Office shall ascertain the latter's current address. In doing so, the Federal Office shall as far as possible avoid indicating the purpose of the inquiry.

2 Federal, cantonal and communal authorities that can provide the relevant information are obliged to assist the Federal Office at its request.

3 The Federal Office shall inform the sperm donor of the fact that his personal data are to be disclosed to the child. It shall grant him an appropriate period to express his wishes concerning personal contact with the child.

Art. 23[36] Provision of information to the child

1 If the requirements of Article 27 paragraph 1 or 2 of the Act are met, the child may choose whether to be provided information:

a. by communication by post;

b. by a doctor, a person trained in social psychology, or a specialist organisation of the child's choice.

2 The personal details of the sperm donor shall be provided to the child in a written report.

3 If the requirement in Article 27 paragraph 1 of the Act is not met, the Office shall inform the child in writing that he or she is not yet entitled to be provided with information.

4 If the requirement in Article 27 paragraph 2 of the Act is not met, the Office shall inform the child in writing that he or she has no legitimate interest and, provided the requirement in Article 27 paragraph 1 of the Act is met, that he or she may choose how information is provided in accordance with paragraph 1.

5 The Office shall notify the child if the donor could not be found or could not be reliably identified, failed to answer or declined any personal contact.

6 It shall advise the child with regard to the counselling options available.

34 Amended by No I of the O of 14 Nov. 2018, in force since 1 Jan. 2019 (AS **2018** 4681).
35 Amended by No I of the O of 14 Nov. 2018, in force since 1 Jan. 2019 (AS **2018** 4681).
36 Amended by No I of the O of 14 Nov. 2018, in force since 1 Jan. 2019 (AS **2018** 4681).

Art. 24[37]

Art. 25 Data protection

[1] In any contacts with the sperm donor or with the child, strict confidentiality shall be observed by the persons and authorities concerned.

[2] Before any contacts with the sperm donor, his identity must be securely established.

Art. 26 Charges

The charges and expenses in the disclosure procedure shall be based on the Ordinance of 27 October 1999[38] on Civil Status Fees.

Chapter 3 Final provisions

Art. 27 Amendment of existing legislation

...[39]

Art. 28[40] Transitional provisions to the Amendment of 21 June 2017

[1] Licence holders under Article 8 paragraph 1 letter a of the Act who are already using reproductive techniques when the Amendment of 21 June 2017 comes into force and who wish to continue with such activities must submit an application to the supervisory authority within three years containing proof that they meet the requirements under Article 4 paragraph 1 hereof. They may continue their activities until the decision of the supervisory authority takes full effect.

[2] Licence holders under Article 8 paragraph 1 letter a of the Act who are already using reproductive techniques with analyses of genetic material from reproductive cells when the Amendment of 21 June 2017 comes into force and who wish to continue with such activities must submit an application to the supervisory authority within three years containing proof that they meet the requirements under Article 9 paragraph 3 of the Act and Articles 4 paragraph 1 and 6 paragraph 2 hereof. They may continue their activities until the decision of the supervisory authority takes full effect.

Art. 29 Commencement

This Ordinance comes into force on 1 January 2001.

37 Repealed by No I of the O of 14 Nov. 2018, with effect from 1 Jan. 2019 (AS **2018** 4681).
38 SR **172.042.110**
39 The amendments may be consulted under AS **2000** 3068.
40 Amended by No I of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).

Annex 1[41]

41 Originally: Annex. Repealed by No II of the O of 31 Oct. 2012, with effect from 1 Jan. 2013 (AS **2012** 6097).

Annex 2[42]
(Art. 4 para. 1 let. c)

Quality management system

European Standard ISO/IEC 17025:2005 (General Requirements for the Competence of Testing and Calibration Laboratories) or ISO 15189:2012 (Medical Laboratories – Requirements for Quality and Competence)[43].

42 Inserted by No II of the O of 21 June 2017, in force since 1 Sept. 2017 (AS **2017** 3651).
43 The standards may be inspected at the Federal Office of Public Health, Schwarzenburgstrasse 157, 3003 Bern, or obtained from the Swiss Association for Standardisation, Sulzerallee 70, 8404 Winterthur; www.snv.ch.

Annex 3[44]
(Art. 2 para. 1[bis] and 1[ter])

Qualification requirements for using assisted reproductive techniques according to the state of the art

Persons are qualified to use assisted reproductive techniques according to the state of the art if they hold:

a. the gynaecological endocrinology and reproductive medicine specialty under the continuing education and training programme of the Swiss Institute for Medical Education of 23 June 2022[45] or an earlier version of this programme; or

b. an equivalent foreign continuing education and training qualification.

44 Inserted by Annex 6 No II 2 of the O of 23 Sept. 2022 on Human Genetic Testing, in force since 1 Dec. 2022 (AS **2022** 585).