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DH-BIO/INF(2016)4

COMMITTEE ON BIOETHICS (DH-BIO)

Replies by the member States to the questionnaire on access to medically assisted procreation (MAP), on the right to know about their origin for children born after MAP and on surrogacy ¹

¹ Updates made in 2020 are indicated by **. The list of countries, which sent their updates in 2020 is on page 3. The <u>section on surrogacy</u> (questions 12 to 15, in Appendix to this document) has been replaced by the more detailed questions. The replies to these new questions on surrogacy are now presented in an Addendum to this document.

Replies by the member States to the questionnaire on access to medically assisted procreation (MAP), on right to know about their origin for children born after MAP and on surrogacy

Explanation of abbreviations

- * indicates that a comment accompanies the response and is presented below the table
- ** indicates an update in 2020
- - means the question was not applicable
- "FYROM" stands for "the Former Yugoslav Republic of Macedonia"

The following countries sent their update in 2020, indicated by ** in this document.

| Country |
|-----------|
| Estonia |
| France |
| Lithuania |

Language of the questionnaire answers:

| Country | English | French | Country | English | French |
|-------------------------|-------------|-------------|------------------------|-------------|-------------|
| Albania | | | Luxembourg | Translation | Yes |
| Andorra | Translation | Yes | | | |
| Armenia | | | Malta | Yes | Translation |
| Austria | Yes | Translation | Republic of Moldova | | |
| Azerbaijan | Yes | Translation | Netherlands | Yes | Translation |
| Belgium | Translation | Yes | Norway | Yes | Translation |
| Bosnia & Herzegovina | Yes | Translation | Poland | Translation | Yes |
| Bulgaria | | | Portugal | Yes | Translation |
| Croatia | Yes | Translation | Romania | | |
| Cyprus | Yes | Translation | Russian Federation | Yes | Translation |
| Czech Republic | Yes | Translation | San Marino | Yes | Translation |
| Denmark | Yes | Translation | Serbia | Yes | Translation |
| Estonia | Yes | Translation | Slovakia | Yes | Translation |
| Finland | Yes | Translation | Slovenia | Yes | Translation |
| France | Translation | Yes | Spain | Yes | Translation |
| Georgia | Yes | Translation | Sweden | Yes | Translation |
| Germany | Yes | Translation | Switzerland | Translation | Yes |
| Greece | Yes | Translation | 'FYROM' | Yes | Translation |
| Hungary | Yes | Translation | Turkey | Yes | Translation |
| Iceland | Yes | Translation | Ukraine | Yes | Translation |
| Ireland | Yes | Translation | United Kingdom | Yes | Translation |
| Italy | Translation | Yes | Canada | Yes | Translation |
| Latvia | Yes | Translation | Israel | Yes | Translation |
| Lithuania | Yes | Translation | | | |

• Extracts of national legislations have been translated by the Division

Questionnaire on access to MAP and on right to know about their origin for children born after MAP

Delegations are invited to reply to the questions, but also, where possible, to provide explanations for the basis for such positions/decisions in their countries.

Section I – Legal regulation or practice and access to MAP

| Relevant legal instruments, draft legal instruments, or practice | | | | | |
|--|---|------------------|--|--|--|
| Title of the law | | | | | |
| | | | | | |
| Date of | adoption and entry into force | | | | |
| Publish | ed in | | | | |
| | e if process of revision is ongoing and, in your answers, provide in in the draft law | | | | |
| | | | | | |
| If no leg | gal instrument please describe the practice | | | | |
| Legal a | spects_ | | | | |
| 1. fertilizat | Is access to medically assisted procreation (MAP) (artificial insemintion procedures (IVF)) | ation, in vitro | | | |
| | a. restricted to heterosexual couples?b. possible for women not living in a heterosexual couple? | YES/NO YES/NO | | | |
| Possible | e, further comments | | | | |
| Medica | aspects aspects | | | | |
| 2. | Are there specific criteria for access to MAP? | | | | |
| | Medical reasons: | | | | |
| | a. Infertility | | | | |
| | i. for a heterosexual couple?ii. for women not living in a heterosexual couple? | YES/NO YES/NO | | | |
| | ii. 101 women not living in a neterosexual couple? | TES/NO | | | |
| | b. Risk of transmission of a disease (please specify the risk ar | | | | |
| | i. for a heterosexual couple?ii. for women not living in heterosexual couple? | YES/NO YES/NO | | | |
| | c. Other Please specify | | | | |
| Possible | e, further comments | | | | |
| Financi | al aspects | | | | |
| 3. | Are MAP procedures covered by the social security system? | YES/NO | | | |
| Ple | ase explain why (e.g. infertility considered as a disease) | | | | |
| Possible | e, further comments | | | | |
| 4. | Are there specific criteria for such coverage (e.g. infertility, age limit)? | VEO/NO | | | |
| Ple | ase explain the basis for such criteria | YES/NO | | | |

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Possible, further comments

Is the financial coverage limited to a number of MAP procedures (e.g. three IVF procedures only)? YES/NO Possible, further comments Sperm/oocyte/embryo donation Are donation of the following permitted in your country? YES/NO a. Sperm b. Oocytes YES/NO c. Embryos YES/NO Possible, further comments Are there specific compensation arrangements for such donation(s) (e.g. financial compensation, reduced fees for a MAP procedure in the case of oocyte donation)? YES/NO Possible, further comments 8. Are there specific criteria for donation of the following? a. Sperm YES/NO b. Oocytes YES/NO c. Embryos YES/NO What are those criteria (e.g. being parents, age limit)? Possible, further comments Are there specific non medical criteria for selection of gametes/embryo to be used for MAP (e.g. matching appearance of donor and future parent(s))? YES/NO Please explain Possible, further comments Are there special measures for the prevention of consanguinity? YES/NO (e.g. official register, limited number of donations) Please explain Possible, further comments In a homosexual couple, is a legal relationship possible between a child and the partner of his or her legal parent? YES/NO Please specify Possible, further comments [Surrogate mothers² 12. Is surrogacy permitted in your country? YES/NO If yes, describe all conditions regulated by law Possible, further comments 13. If yes, can the surrogate mother be legally remunerated? YES/NO Please explain

² Please note that the section on surrogacy (questions 12 to 15) have been replaced by the more detailed questions (questions 1 to 20), listed in the Annex I to this document.

Possible, further comments

14. If surrogacy is forbidden in principle, are there exceptions?

YES/NO
Please explain

Possible, further comments

15. Are you aware of illegal practices in your country?

YES/NO

Possible, further comments]

Section II - Right to know about their biological origin for children born after MAP

16. Are donation of the following anonymous?

| a. Sperm | YES/NO |
|------------|--------|
| b. Oocytes | YES/NO |
| c. Embryos | YES/NO |

Please explain what legal provisions

Possible, further comments

17. Is it possible to obtain information about the biological origin of a child born after gametes or embryo donation?

| i. For the child him or herself | YES/NO |
|---------------------------------|--------|
| ii. For the parents | YES/NO |
| iii. For a court | YES/NO |

In particular:

a. Identity of the donor(s)

| i. For the child him or herself | YES/NO |
|---------------------------------|--------|
| ii. For the parents | YES/NO |
| iii. For a court | YES/NO |

b. Certain health information concerning the donor(s)

| i. For the child him or herself | YES/NO |
|---------------------------------|--------|
| ii. For the parents | YES/NO |
| iii. For a court | YES/NO |

c. Other information

| i. For the child him or herself | YES/NO |
|---------------------------------|--------|
| ii. For the parents | YES/NO |
| iii. For a court | YES/NO |

Please explain legal provisions and procedures to be followed

Possible, further comments

18. Is it possible to contest maternity and paternity of children born utilising MAP and under which conditions (family law provisions)?

YES/NO

Possible, further comments

<u>Section III – Current debate and specific situations met in your country, in relation to these issues</u>

- 19. Is there an important current debate in your country on these or related issues? If so, what might the implications be (e.g. changes to the legal situation)?
- 20. Delegations are invited to provide information, in this section, on particular cases encountered in their country, and especially their case-law, in relation to the questions appearing in Sections I and II above.

REPLIES

Section I – Legal regulation or practice and access to MAP

Relevant legal instruments, draft legal instruments, or practice

<u>Andorra</u>

Title of the legislation: Law 12/2019, of the 15th February, described as techniques of assisted reproduction

Date of adoption and of entry into force: adopted on 15.02.2019 and came into force on 21.03.2019

Published in the Official Bulletin of the Principality of Andorra (B.O.P.A)

Austria

Title of the law: Law on Medical Assisted Reproduction "Fortpflanzungsmedizingesetz"

Date of adoption: 14 May 1992 entry into force 1 July 1992

Published: in Federal Gazette "Bundesgesetzblatt" BGBI. Nr. 275/1992 **Amendment:** Fortpflanzungsmedizinrechts-Änderungsgesetz 2015 **Date of Adoption**: 23 February 2015, entry into force: 24 February 2015 **Published in**: Federal Gazette "Bundesgesetzblatt" BGBI. I Nr. 35/2015

Revision concerning egg donation, sperm donation and PGD

Azerbaijan

Title of the law: No specific law, but different articles in the Code:

Law of population health protection

Date of adoption: 26 June 1997; entry into force: 24 September 1997.

Chapter 5.

Article 29 Artificial insemination and embryo implantation.

Article 40. The usage of semen and human organs for transplantation.

The Criminal Code of Azerbaijan Republic

Date of adoption: 30 December 1999; entry into force: 01 September 2000

Chapter 8.

Article 136. Illegal Artificial insemination.

Belgium

Title of the law: Medically Assisted Procreation and Destination of Supernumerary Embryos and Gametes Act of 6 July 2007

Entry into force 27 July 2007

Published in: the Moniteur belge [Official Gazette] on 17 July 2007, p.38575

Articles 26 and 55, paragraph 2, of the Act, inserted by a law of 10 April 2014 and entered into force on 10 May 2014 provides that if the two authors of the parental project are two women, they are considered as a single woman, when counting the maximum of six women who can give birth to children from gametes or surplus embryos from one donor or donor couple.

Bosnia & Herzegovina

Bosnia and Herzegovina still have no specific legislation on MAP covering entire country. Currently, MAP is regulated by the Health Insurance legislation bylaws (in both B&H entities: Federation BiH and REpublika Srpska and Brcko District BiH), mainly regulationg the rights of the couple to reimbursement of IVF costs for two procedures.

Date of adoption and entry into force:

Federation BIH: Decision on Establishment of Basic Patients Rights

http://mz.ks.gov.ba/sites/mz.ks.gov.ba/files/Odluka%20o%20utvrdjivanju%20Osnovnog%20paketa%20slnFBiH21-09.pdf chapter X (11.,12.)

Adopted on 19. March 2009, in force as of 01.04.2009

Published in: Službene novine Federacije BiH", 21/09 od 01. 04.2009.

In the entity Republika Srpska and Brcko district, Health Insurance Fund endorse budget for MAP each year, depending on the funds availability

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law

MAP as a medical procedure is well established both in public and private sector in Bosnia and Herzegovina.

A draft Law on Medically Assisted Reproduction in the entity Federation B&H, after two years of preparation by the Federal Ministry of Health, and extensive public debate, <u>has been rejected</u> by the Parliament of Federation B&H in June 2014 https://www.google.ba/#q=+nacrt+zakon+o+biomedicinski+potpomognutoj+oplodnji

In 2016. B&H state level Parliamentary Group on Gender Equality drafted the B&H Framework Law on MAP (Setting standards for the entire country); however, despite support by the Council of Ministers of B&H, it has been rejected by Constitution-legal Commission of the House of Representatives, not for the content, but for the political reason. http://static.parlament.ba/doc/46496_ZAKON%20O%20LIJE%c4%8cENJU%20NEPLODNOS TI BIH%20%20nacrt %20pre%c4%8di%c5%a1%c4%87eni%20(1). (July 2016)

Currently (January 2017) the new draft law on MAP (proposed by the Socialist Democrat Party MS) is in the Parliamentary procedure in B&H Entity Federation BIH, while the Draft of the MAP law prepared by the competent Ministry of Health will be on the Parliament agenda in 2017 as well.

Croatia

Title of the law: Act on Medically Assisted Fertilisation

Date of adoption and entry into force: Adopted on 18th July 2012.

Entered into force: 4th August 2012.

Published in: Official Gazette No 86 from 27th July 2012

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: Revision of the Act is planned for the last quarter of the 2016. Revision will be primarily focused on the technical aspects, i.e. harmonisation with acquis communautaire in this field (EU tissues and cells directives).

Cyprus Cyprus

Title of the law: Not Applicable

Czech Republic

Title of the law: Czech Act on Specific Health Services (Act No. 373/2011 Sb.) and related

aws

Date of adoption and entry into force: Adoption 8.12.2011, force 1.4.2012

Published in Collection of Laws

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: Revisions are discussed continuously

Denmark

Title of the law: Act on medically assisted procreation in connection with medical treatment, diagnosis and research etc. (Loi no. 460/1997)

Date of adoption and entry into force: 1 October 1997

Published in Danish Law Journal

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: The law was last *recently amended in December 2018*.

Estonia**

Title of the law: Artificial Insemination and Embryo Protection Act

Date of adoption and entry into force: 11 July 1997

Amended: 01/01/2018

Published in: State Gazette 1997, Nr. 51. Art 824

Finland

Title of the law: Act on Assisted Fertility Treatments (laki hedelmöityshoidoista; 1237/2006)

Date of adoption and entry into force: 22/12/2006; 1 September 2007

Title: Decree of the Ministry of Social Affairs and Health on Assisted Fertility Treatments

(Sosiaali- ja terveysministeriön asetus hedelmöityshoidoista; 825/2007) **Date of adoption and entry into force:** 29/8/2007; 1 September 2007 **Published in:** Statute Book of Finland (Suomen säädöskokoelma)

France**

Laws and regulations

French Bioethics Law No. 2011-814 of 7 July 2011

Ordinance No. 2008-480 of 22 May 2008 implementing Directive 2004/23/CE of the European Parliament and of the Council of 31 March 2004 on gamete donation and medically assisted procreation

Date of adoption and entry into force

First bioethics laws adopted in 1994, last revision: Law No. 2011-814 of 7 July 2011, which entered into force on 9 July 2011

Ordinance No. 2008-480 of 22 May 2008, which entered into force on 24 May 2008.

Published in : Official Journal of the French Republic (*Journal officiel de la République française*)

Next revision: 2018, currently under revision

Georgia

Title of the law:

- a) The law of Georgia on Health Care (LHC) Chapter XXIII Family Planning
- b) The Draft law on Reproductive Health and Reproductive Rights (DL-RHRR)

Date of adoption and entry into force:

- a) LHC Adopted by Parliament of Georgia on 10 December 1997
- b) DL-RHRR- Submitted to the Georgian Government in December 2003

Published in: LHC - News of the Parliament, 1997, Dec.

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: DL-RHRR- Before submitting the draft law to the Government, it was discussed among main stakeholders within the healthcare system and relevant non-governmental organizations. Professor of Toronto University Bernard Dickens (expert in the field of health law) was involved in the drafting process.

Later the document was sent to the various Ministries, Departments and governmental agencies and their comments have been taken into consideration as well.

The next steps should be: (a) discussions within the apparatus of the President and later (b) debates in the Parliament.

Germany

Title of the law:

- a) Act on the Protection of Embryos [Embryonenschutzgesetz];
- b) section 27a of Book V of the Social Code [Fünftes Buch Sozialgesetzbuch];
- c) sections 1591 to 1600e, 1682, 1685 of the Civil Code [Bürgerliches Gesetzbuch];
- d) section 9 of the Act on Registered Life Partnerships [Lebenspartnerschaftsgesetz];
- e) section 8b of the Transplantation Act [Transplantationsgesetz];
- f) Tissues and Cells Regulation of the Transplantation Act [TPG-Gewebeverordnung]

Date of adoption and entry into force:

- a) 13 December 1990; 1 January 1991
- b) Civil Code as amended by the Act to Further Improve Children's Rights [Gesetz zur weiteren Verbesserung von Kinderrechten (Kinderrechteverbesserungsgesetz)]: 9 April 2002; 12 April 2002
- c) 16 February 2001; 1 August 2001
- d) 14 November 2003; 1 January 2004
- e) 20 July 2007; 1 August 2007
- f) 26 March 2008; 5 April 2008

Published in:

- a) German: http://www.gesetze-im-internet.de/eschg/
- b) German: http://www.gesetze-im-internet.de/bgb/
 - English: http://www.gesetze-im-internet.de/englisch_bgb/
- c) German: http://www.gesetze-im-internet.de/lpartg/
 - English: http://www.gesetze-im-internet.de/englisch_lpartg/
- d) German: http://www.gesetze-im-internet.de/sgb_5/
- e) German: http://www.gesetze-im-internet.de/tpg/
- f) German: http://www.gesetze-im-internet.de/tpg-gewv/

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: No ongoing revision

If no legal instrument please describe the practice:

Model Guidelines of the German Medical Association on the performance of assisted reproduction as the description of the current medical (professional) standard [(Muster-) Richtlinie der Bundesärztekammer zur Durchführung der assistierten Reproduktion - Novelle 2006 – als Beschreibung des aktuellen ärztlichen (Berufs-) Standards] (Deutsches Ärzteblatt 2006; 103 [20]: p A 1392 – A 1403)

New version of paragraph 5.4.1 (documentation) of the Model Guidelines (Deutsches Ärzteblatt 2014; 111 [13]: A 554)

Both laws are in force now in Greece:

Title of the law: "Medical assistance on human assisted procreation" Law 3089/2002, State Journal (FEK) No 327.

Date of adoption and entry into force: 20th of December 2002

Published: 23 of December 2002 This law mostly regulates issues of affiliation with the child to be born by medically assisted reproduction. This law also legalizes post-mortem insemination and surrogate motherhood, under certain conditions which are specified in the relevant articles.

Title of the law: "Application of medically assisted procreation" Law 3305/2005, State Journal (FEK) No 17

Date of adoption and entry into force: 26th of January 2005.

Published: 27 January 2005

In 2005, Law 3305 was enacted regarding Medically Assisted Procreation in Greece. Whereas the previous law 3089 regulates mainly issues of affiliation of the child to be born with her parents, this law supplements the previous one and mainly regulates the way in which Units of MAP function. It describes the methods of MAP, conditions of application, informed consent issues, cryopreservation of gametes, gamete donation, embryo research, surrogacy, traceability etc. Moreover it provides for both administrative and penal sanctions for the perpetrators in case of violation of the law. It also establishes the responsible control mechanism, namely the National Authority for Medically Assisted Reproduction. According to this law methods of MAR are applied in a way which safeguards respect to the freedom of the individual and the right to development of personality (i.e. a right protected by the Greek Constitution), as well as the satisfaction of the desire to have a child, always according to the principles of Bioethics. The law further stipulates that the above mentioned application shall always take into consideration the welfare of the child to be born.

Hungary

Title of the law: Health Act, Act CLIV of 1997, Chapter IX (further: Act)

Date of adoption: 23.12.1997 entry into force: 01.07.1998

Published in: Magyar Közlöny Nr 119, 1997

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law:

not actually

Title of the law: decree Nr. 30/1998 of the Minister of Welfare (further: Decree)

Date of adoption: 24.06.1998 entry into force: 01.07.1998

Published in Magyar Közlöny Nr. 54, 1998.

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law:

intention of revision in the near future

Iceland

Title of the law: Artificial Fertilisation Act N° 55/1996 Date of adoption and entry into force: 1 June 1996

Published in: http://eng.heilbrigdisradunevti.is/laws-and -regulations/nr/685

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: No process of revision has yet been embarked upon, a parliamentary resolution on the necessity of a revision, specifically with regards to issues pertaining to embryonic stem cell research, is being discussed.

Ireland

Until recently in Ireland the provision of assisted human reproduction (AHR) services was largely unregulated. However, in April 2015 Parliament passed the Children and Family Relationships Act which deals with the limited topic of parentage in the case of donor assisted human reproduction. Under the Children and Family Relationships Act 2015, gamete and embryo donation are permitted on a non-anonymous basis. In addition, this legislation provides for the establishment of a national register of gamete/embryo donors, recipients and donor-conceived children (the National Donor-Conceived Person Register), which will allow donor-conceived children to access certain information regarding the gamete/embryo donor involved in procedures leading to their conception.

Moreover, although AHR services are not currently regulated by any specific health legislation, in February 2015, the Minister for Health received Government approval to draft a General Scheme of legislative provisions which would deal with a wide range of issues from the beginning to the end of the AHR process. Following the completion of the General Scheme, the Government approved its publication and the drafting of a Bill on assisted human reproduction based on this General Scheme. The drafting of this Bill is currently ongoing.

Under the proposed legislation, a number of practices will be regulated, including gamete and embryo donation, surrogacy and the assignment of parentage in such cases, pre-implantation genetic screening/diagnosis, sex selection for medical purposes, and posthumous assisted reproduction as well as associated research. It is also proposed that the legislation will establish a regulator to promote patient safety and good clinical practice in the area of assisted human reproduction. The regulator will maintain the National Donor-Conceived Person Register, establish the National Surrogacy Register and maintain records of all assisted human reproduction activities and services.

In January 2018 the General Scheme was submitted to the relevant parliamentary committee for review as part of the pre-legislative scrutiny process. This committee published the report of its review in July 2019, making recommendations which include proposals related to both broad policy objectives and more technical amendments. Its recommendations are being considered during the ongoing process of drafting the AHR Bill.

Italy

Title of the law: Rules Concerning Medical Assisted Procreation **Date of adoption and entry into force** 19 February 2004 NO.40

Published in: Gazzetta Ufficiale della Repubblica Italiana (the official publication containing

details of new laws)

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law:

On 12 June 2005 a popular referendum was held to amend several parts of this law. The repeal of these points was rejected with 74% abstentions (51% of the vote is needed in order to change it).

Summary

1. Protection of the desire to become a mother or a father and rules on the exercise of the rights guaranteed by Law No. 40/2004.

<u>Access</u> to assisted reproduction technology (ART) is restricted to adult heterosexual couples who are married or living together, both alive and at the reproductive stage of their lives. It is prohibited in the case of single persons and homosexuals.

All couples requesting medically assisted procreation (MAP or ART) must produce a medical certificate confirming a sterile or infertile condition for which no other solution is possible.

Before the couple give their written <u>consent</u>, which they are free to withdraw until the in vitro fertilisation of the oocyte takes place, they must be given full technical, legal and ethical information and information about the cost of the procedures and the possible effects of ART on the unborn child.

At the interview with the person responsible of the medical centre, couples are also informed of the possibility of adopting a child or fostering one with a view to adoption (Law No. 184 of 4 May 1983).

Couples must be allowed seven days to reflect on their decision before ART procedures begin.

ART is applied progressively, on the basis of the principle of minimum invasiveness, in order to avoid operations whose technically and psychologically invasive nature make them more arduous.

The doctor in charge of the medical centre is entitled to decide not to proceed with ART for exclusively medical or health reasons.

Cryoconservation of male and female gametes is authorised, provided that the persons concerned are informed and give their written consent.

The law in the original formulation prohibited the use of heterologous techniques (gametes donation was not allowed by a person other than the members of the couple). The intervention of the Constitutional Court (ruling n° 162 of 2014) abolished the prohibition.

2.Protection of the unborn child

<u>The legal status of a child</u> born using ART is that of a legitimate child or a child recognised by the couple. Repudiation of paternity is prohibited, in case of heterologous fertilization. Gamete donors have no legal parental ties with the child that is born (no rights and no duties).

Mothers are no longer entitled to declare at birth that they wish to remain anonymous, as they are authorised to do in cases of natural conception (Presidential Decree No. 396 of 3 November 2000).

3. Protection of the embryo

It is forbidden to freeze or destroy embryos, subject to the provisions of Law No. 194 of 22 May 1978 (the law on the termination of pregnancies).

The original formulation of the law stated that techniques for the production of embryos must not, with due regard for technological and scientific developments and what may be decided in the future on the basis of Ministry of Health legal guidelines, result in the production of a larger number of embryos than is strictly necessary for a single simultaneous transfer, and under no circumstances may more than three embryos be produced

If it proves impossible for the embryos to be transferred to the uterus for a serious, documented reason which is linked to the woman's health and was unforeseeable at the time of fertilisation, cryoconservation of the embryos is authorised until the transfer can take place, provided that it takes place as soon as possible. After ruling **n° 151/2009** of the Constitutional Court, the determination of the number of embryos to be produced and transferred in a contestual implant must be produced in a number strictly necessary for the procreation But this number is demanded to the discretion of the physician, taking into consideration the health condition of the woman.

Under the law on medically assisted procreation, it is forbidden to remove embryos in the event of multiple pregnancies, save in the cases provided for in Law no. 194 of 22 May 1978 (the law on the termination of pregnancies).

The persons referred to in Section 5 of the law are informed of the number and, if they so request, of the development of the embryos produced for transfer to the uterus.

Following **ruling n° 96 of June 5th 2015**, the Constitutional Court lifted the ban preventing fertile couples, known to be carriers of severe genetic diseases, from accessing pre-implantation genetic diagnosis. The mentioned diseases shall meet the severity criteria set out in Article 6, paragraph 1, letter b) of Law N° 194, 22 May 1978, and be detected by relevant public healthcare providers. It is up to the Parliament to identify the criteria for the recognition of these structures.

All experiments on human embryos are prohibited.

Clinical and experimental research on human embryos is authorised provided that its purposes are exclusively therapeutic and diagnostic and that the aim is to safeguard the embryo's health and development.

It is prohibited:

- (a) to produce human embryos for the purposes of research or experiments or for any purpose other than those provided for in the law. Ban on embryo donations for research purposes: In Case of Parrillo v. Italy (no. 46470/11) of 27 August 2015, The European Court of Human Rights acknowledged that banning the donation by a woman, of embryos obtained from in vitro fertilisation to scientific research was not contrary to respect for her private life (there was no violation of Article 8 (right to respect for private life) of the European Convention on Human Rights. It also contended that human embryos could not be reduced to "possessions". The Court considered that Italy was to be afforded a wide margin of appreciation in this case, which raised sensitive moral and ethical issues, and since there was no European consensus on the delicate question of the donation of embryos not destined for implantation. The Consitutional Court has rejected a recent appeal on the topics, saying that the legislator should modify the law.
- (b) to select embryos or gametes for eugenic purposes or to engage in operations designed, by means of selection or manipulation techniques or artificial processes, to alter the genetic make-up of embryos or gametes or to predetermine their genetic characteristics, except in the case of intervention for diagnostic or therapeutic purposes. However, **ruling n° 229/2015** of the Constitutional Court removed the prohibition of embryo selection, only under specific circumstances, determining that it is not a crime in cases where it is aimed at preventing the implantation of embryos born by couples at risk of transmitting severe genetic pathologies, as stated in art. 6, 1 B of the law 194 (on interruption of pregnancy) in identified public structures. Therefore, challenging the constitutionality of Article 13 (paragraphs 3, letter b) and 4) of Law n° 40/2004. This judgment is in line with the ruling mentioned above.

The mentioned judgment nevertheless emphasised the human embryo's entitlement to necessary protection, recalling that "the need to protect the dignity of embryos is envisaged, to which no answer may currently be given other than cryoconservation. An embryo, whatever the more or less ascertainable legal status connected with the beginning of life, certainly cannot be reduced to mere biological matter".

- (c) to carry out cloning through nuclear transfer, early embryo splitting or ectogenesis for the purposes of procreation or research;
- (d) to fertilise a human gamete with a gamete from a different species or to produce hybrids or chimeras.

4. Penalties

Law 40/2004 provides for various progressive penalties where the law has been infringed, applying to doctors and certified centres practising ART.

Men or women to whom these techniques are applied can be punished only if they have failed to follow the proper procedures. The punishment of heterologous insemination has been abolished. Except for the latter, remaining penalties are set out in Article 12 of Law n° 40/2004.

5.Authorisation

Provision is made for a system of regional authorisation for bodies considered to be suitable for certification on the basis of:

- (a) their technical, scientific and organisational features;
- (b) the qualifications of the staff.

The requisite conditions are determined by regional legal instruments.

There is a <u>compulsory register</u> of certified bodies, drawn up and kept by the National Health Institute (. It monitors the use of medically assisted procreation techniques and the embryos produced and children born as a result.

The National Health Institute prepares the annual report that is submitted to the Italian Parliament.

After ruling n° 162/2014, the Ministry of Health has approved Guidelines for the application of heterologous reproductive techniques, with regard to the couple who receives the gamete.. ON the donation of gametes, Italy is going to adopt DIR. UE 2006/17, ALL.III, PAR.3,4 and fllowing modifications. The text is going to be approved in the systems of norm (in the formo f a rule of the government). One key element deriving from the Italian legal system is that oocyte and sperm donation must be a voluntary, altruistic, unpaid act.

Latvia

Title of the law "Law on reproductive and sexual Health" **Date of adoption** 31 January 2002 **and entry into force** 01 July 2002 **Published in** 19 February 2002

Lithuania

Title of the law: The Law on Medically Assisted Procreation of the Republic of Lithuania (The

Law on MAP)

Date of adoption: 14th September 2016

Entry into force: 1st January 2017 (The Law on MAP art. 17.1)

Luxembourg

It is note-worthy that MAP is not currently regulated in Luxembourg, except that:

- Article 312 of the Civil Code states that a repudiation of paternity by the husband of the
 mother is non-admissible "if it established by all proven means that the child has been
 conceived by means of artificial insemination, whether by the husband or by a third party
 with the written consent of the husband.
- The national hospital plan, adopted in 2001 by regulation, provides for the creation of a MAP department in a general hospital with an obstetrics department.

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: There is a proposed law, in fact a draft law initiated by Parliament, concerning MAP. Parliament had planned a large general debate but this has not yet taken place.

Malta

Medical Assisted Procreation and Surrogacy are being discussed at the moment in Malta for an update on the law. There is some controversy of course but only a proposed amendment.

The proposals are to preserve a limited number of embryos (5)

To introduce surrogacy – but Minister is going to put this out for discussion.

To introduce gamete banking with anonymity (again the question of anonymity is being debated)

Provision of IVF for single parents as well as same-sex couples.

Netherlands

Title of the law:

- Wet houdende regels inzake handelingen met geslachtscellen en embryo's (Embryowet) (= Act containing rules relating to the use of gametes and embryos) (Embryos Act). Next to that, a Guideline from the Dutch Society for Obstetrics and Gynaecology states medical criteria. Furthermore it specifies practices with regard to for instance in vitro fertilization, the storage of embryos, oocyte- donation.
- Wet Bijzondere Medische Verrichtingen (= Act on special medical operations). This act, and the lower legislation based on it, require clinics to have permission of the Minister of Health to perform in vitro fertilization.

Date of adoption and entry into force: Embryos Act: 20 June 2002 - Act on special medical operations 24 October 1997.

Published in: Staatsblad van het Koninkrijk der Nederlanden

Norway

Title of the law: The act relating to the application of biotechnology in human medicine etc

Adopted 5 December 2003, partly into force from 1 January 2004, 1 September 2004 and 1 January 2005. Limited use of PGD was allowed (only in cases of X-linked diseases), and research on surplus embryos was banned. An amendment in force from September 2004 allowed PGD also in cases of serious hereditary diseases for which no treatment is available. New regulations regarding PGD and research on surplus embryos entered into force in July 2008; allowing research on surplus embryos under certain conditions, and PGD or PGD/HLA in situations of serious hereditary disease. New regulations regarding access to MAP for lesbian couples entered into force in January 2009. In 2013 the act was amended to allow MAP to otherwise fertile couples, where one person has a serious and chronic sexually transmitted infection.

Indicate if process of revision is ongoing: the Act is currently under evaluation.

Poland

Title of the law: There are no general laws or regulations on medically assisted procreation in Poland

If no legal instrument please describe the practice: In view of the lack of specific legal provisions, MAP may be practised under the general rules of medical law and in particular those governing the practice of medicine (duty to inform patients of the medical and legal consequences, confidentiality with regard to the MAP itself and the identity of the donor of the gametes, due care in the choice of the donor and examination of the genetic material to be used, the duty to obtain free and informed consent, etc), the corresponding rights of patients, the general laws on families, descent and registration, and the Medical Code of Ethics (which does not address this issue specifically). Some questions are addressed in the Opinion of the Polish Association of Obstetricians concerning the MAP techniques used in the treatment of infertility, and others by the internal regulations of the clinics practising MAP (practice may therefore vary from one place or establishment to another).

Portugal

Title of the law Law: 17/2016 Enlarges those who can benefit from ART (June 20, 2016)

Date of adoption and entry into force: August 1, 2017

Published in: Diário da República, la série – No 116, pp 1903-1904, June 20, 2016

Russian Federation

Title of the law: The Federal Law "On Fundamentals on Protection of Citizens Health" 2011 No. 323-FZ (s. 55 specifically).

Date of adoption and entry into force: adopted – 21 November 2011; enacted – in part it related to MAP (s. 55) – on 01 January 2012.

Published in: "Rossiiskaya gazeta" of 23 November 2011, No 263

Title of the law: The Family Code 1995 (as amended) (ss. 51-52 especially).

Date of adoption and entry into force: adopted – 29 December 1995; enacted – 01 March 1996.

Published in: "Sobranie Zakonodatelstva RF" 01 January 1996, № 1, s.16.

Title of the law: The Federal Law on Acts of Civil Status 1997 (as amended) (especially s.16 (5))

Date of adoption and entry into force: adopted -15 November 1997; enacted – on the day of official publication

Published in "Sobranie Zakonodatelstva RF", 1997, № 47, s. 5340

Title of the law: RF Ministry of Health Order of 30 August 2012 № 107н "On the Order of Use of Assisted Reproduction Technologies, Contraindications to Them, and Their Limitations" (Regulations).

Date of adoption and entry into force: registered with the RF Ministry of Justice on 12 February 2013, enacted ten days after official publication

Published in "Rossiiskaya Gazeta", of 11 April 2013, No 78/1.

San Marino

There is no specific law in Republic of San Marino. In the case of infertility heterosexual couples are guaranteed links with the Italian reference centers to proceed with MAP. All questions related to MAP with the possible donation of gametes are the same answers as for Italy.

Serbia

Title of the law: Law on Infertility Treatment with the Procedures of Biomedically Assisted Fertilization

Date of adoption and entry into force: adoption 2009; entry into force 01.01.2010

Published in: "Official Gazette of the Republic of Serbia", No. 72/2009

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: At the moment, new law is in the process of adoption by the Serbian Parliament. Public debate is finished and new law is correlated with EU Directives

Slovakia

If no legal instrument please describe the practice There is no law regulating particular assisted reproduction techniques, but these methods are generally permitted. For insurance, basic problems of MAP are partially solved by the Sanitary Order Law / there are definitions of indications, contra – indications for reimbursement of MAP are: more than 38 years of age, tubal sterility or previous interruption for social or personal reasons. There are reimbursement only for 2 cycles of MAP.

Slovenia

Title of the law: The Law on treatment of infertility and procedures of fertilization with biomedical assistance (Zakon o zdravljenju neplodnosti in postopkih oploditve z biomedicinsko pomočjo (ZZNPOB))

Date of adoption and entry into force 28 July 2000 / 8 September 2000

Published in Uradni list RS 70/2000 z dne 8 August 2000 (Official Gazette of the Republic of Slovenia, 8 August 2000, 3307).

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: Not at present

Spain

Title of the law: Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida (Law 14/2006 on assisted reproductive techniques)

Date of adoption [and entry into force]: 26 May 2006

Published (entry into force) in: Boletín Oficial del Estado nº 126, 27 May 2006 (the modification of this law has been published in Boletín Oficial del Estado nº 167, 15 October 2015).

Title of the law: Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización (Royal Decree 1030/2006, of 15 September, establishing the portfolio of common services of the National Health System).

Date of adoption [and entry into force]: 16 September 2006

child and one of the parents but to not allow surrogacy.

Published (entry into force) in: Boletín Oficial del Estado nº 222, 16 September 2006

Sweden

Title of the law: Lagen (2006:351) om genetisk integritet (The Act on Genetic Integrity)

Date of adoption and entry into force: Adopted 18/5/2006 and entered into force 1/7/2006. **Published in:** Svensk Författningssamling, SFS

Amendments in the law will enter into force on April 1st 2016, allowing single females to be fertilized by assisted reproduction. The egg cell has to be the single female's own gametes. The questions about the requirement of a) a genetic link between one of the parents and the child, and b) whether altruistic surrogacy, if any, should be allowed, were recently assessed. The government inquiry "Olika vägar till föräldraskap (SOU 2016:11)" has in a publication on the 24th February 2016 proposed to remove the requirement of a genetic link between the

Switzerland

Title of the law: Federal Act on Medically Assisted Reproduction (Reproductive Medicine Act, RMA), Reproductive Medicine Ordinance (RMO)

Date of adoption and entry into force RMA: 18.12.1989 / 1.1.2001 and RMO: 4.12.2000 / 1.1.2001

 $\label{eq:published} \textbf{Published in:} \ \underline{\text{https://www.admin.ch/opc/fr/classified-compilation/20001938/index.html}} \ , \ \text{and https://www.admin.ch/opc/fr/classified-compilation/20002342/index.html} \ .$

Revision: June 5th,2016, popular vote on the revision of the RMA regarding the regulation of PGS/PGD (prohibited until now)

Turkey

Title of the law: By Law (Regulation) on Centres for Treatment (for medically assisted procreation) - Üremeye Yardimci Tedavi (Üyte) Merkezleri Yönetmeligi

Date of adoption and entry into force: 31 March 2001

Published in Official Gazette

Ukraine

Title of the law:

- 1) Decree of the Ministry of Health dtd 4 February 1997
- 2) Family Code of Ukraine dtd 1 January 2004
- 3) Decree N52/5 of the Ministry of Justice dtd 18 October 2000

Date of adoption and entry into force: 1 january 2004

Published in: Vydavnychiy dim 'Kuïb' 2004

United Kingdom

Title of the law: Human Fertilisation and Embryology Act 2008; Human Fertilisation and Embryology Act 1990 (as amended)

Date of adoption and entry into force:

Human Fertilisation & Embryology Act 1990 date of adoption and entry into force: 1 August 1991

HFEA Act 2008 received Royal assent on 13 November 2008. The HFE Act 2008 came into force in three stages:

Phase one: On April 6 2009 part 2 of the Act, the revised definitions of parenthood, took effect.

Phase two: In October 2009 the amendments to the 1990 legislation take effect. Examples of these amendments include research on human admixed embryos, and removal of the 'need for a father'.

Phase three: In April 2010 people in same sex relationships and unmarried couples are able to apply for orders allowing them to be treated as parents of children born using a surrogate. Phase four: In January 2019 single people are able to apply for orders allowing them to be treated as parents of children born using a surrogate.

Canada

Title of the law: An Act relating to assisted human reproduction and related research ("the Act").

Date of adoption and entry into force: The Act received Royal Assent on 29 March 2004. The provisions of the Act will come into force in stages. The first set of provisions came into force on 22 April 2004.

Published in: Statutes of Canada 2004 chapter 2.

Indicate if process of revision is ongoing and, in your answers, provide information on provision in the draft law: Section 70 of the Act provides that within three years after the coming into force of the provision establishing the Assisted Human Reproduction Agency of Canada (s. 21), the administration of the Act shall be reviewed by any committee of the Senate, the House of Commons or both Houses of Parliament.

Israel

Title of the law:

- (1) Regulations of IVF
- (2) Agreement of foetus carrying act (surrogate mothers)
- (3) Donation of ovules act (still in draft)

Date of adoption and entry into force: Regulations of IVF – 1987 – Agreements - 1996

Legal aspects

- 1. Is access to medically assisted procreation (MAP) (artificial insemination, in vitro fertilization procedures (IVF)
 - a. restricted to heterosexual couples?
 - b. possible for women not living in a heterosexual couple?

| Country | а | b | Country | а | b |
|-------------------------|------|------|-----------------------|------|------|
| Albania | | | Luxembourg | No | Yes* |
| Andorra | No | Yes | | | |
| Armenia | | | Malta | * | * |
| Austria | No* | Yes* | Republic of Moldova | | |
| Azerbaijan | Yes | Yes | Netherlands | No | Yes* |
| Belgium | No* | Yes | Norway | No* | Yes* |
| Bosnia & Herzegovina | Yes | No* | Poland | Yes* | No* |
| Bulgaria | | | Portugal | No* | Yes* |
| Croatia | No | Yes | Romania | | |
| Cyprus | Yes | No | Russian Federation | Yes* | Yes* |
| Czech Republic | Yes | No | San Marino | -* | |
| Denmark** | No* | Yes* | Serbia | Yes | Yes |
| Estonia | Yes | Yes | Slovakia | Yes | No |
| Finland | No* | Yes* | Slovenia | Yes* | No |
| France | Yes* | No* | Spain | Yes* | Yes* |
| Georgia | * | * | Sweden | No | Yes* |
| Germany | Yes* | No | Switzerland | Yes | No |
| Greece | Yes* | Yes* | "FYROM" | Yes | No |
| Hungary | Yes* | Yes* | Turkey | Yes | No |
| Iceland | Yes | No | Ukraine | No* | Yes* |
| Ireland | _* | -* | United Kingdom | No | Yes* |
| Italy | Yes | No | Canada | No* | Yes* |
| Latvia | No | Yes | Israel | No* | Yes |
| Lithuania | Yes | No | | | |

Austria

Access for homosexual and heterosexual couples, no access for single women.

<u>Belgium</u>

The 2007 Act makes no mention of such a restriction. Each centre is free to accept or refuse requests from homosexual couples.

Bosnia & Herzegovina

Currently No, but envisaged in the new draft legislation.

Denmark

There are no restrictions in the access to medically assisted procreation neither to hetero couples or single women.

Finland

The national legislation is based on the concepts of a "couple" (that is, a woman and a man living together in marriage or in a relationship comparable to marriage or two women living together in marriage, registered partnership or in a relationship comparable to marriage) and a "person receiving treatment" (a couple or a woman not living in a marriage, registered

partnership or a relationship comparable to marriage). The provisions in certain sections of the Act vary depending on whether the treatment is provided to a couple or to a single woman.

Clinics in the public sector have declined to provide MAP to female couples and single women, on the grounds that these services are provided only on the basis of medical indications. Female couples and single women have for this reason sought services from the private sector.

France**

Access is restricted to couples composed of a man and woman, both alive and of reproductive age, and who have already consented to embryo transfer or insemination. The following are impediments to insemination or embryo transfer: death of one of the members of the couple, filing of a petition for divorce or legal separation or couple no longer living together, and withdrawal of consent by either member of a couple communicated in writing to the physician supervising the medically assisted procreation programme.

The bioethics bill, currently under discussion in the Parliament, envisages giving access to MAP to single women and female couples, removing the criterion of pathological infertility prerequisite to have recourse to it.

Hungary

Restricted to health condition (infertility) or age consideration connected with health

Georgia

a. LHC: Insemination-No; IVF-Yes

- a) At present the law gives access to artificial insemination to heterosexual couples as well as to single women.
- b) However in vitro fertilization (IVF) is accessible only to couples.

DL-RHRR: No

Draft law gives access to medically assisted procreation (artificial insemination as well as in vitro fertilization procedures) to heterosexual couples as well as to single women.

b. LHC: Insemination-Yes; IVF-No

- a) Law gives access to artificial insemination to single women. However, the Law does not specify whether women should be living in heterosexual couple or not.
- b) IVF is not accessible for single women.

DL-RHRR: Yes

Draft law gives access to medically assisted procreation (artificial insemination as well as in vitro fertilization procedures) to single women.

Germany

Restrictions are based on the Model Guidelines of the German Medical Association.

Greece

The law stipulates that all adult persons have the right of access to methods pf MAP and for women the age limit is 50 years of age. Persons under 18 years of age have exceptionally the right of access only in case of a very serious disease. The law only refers specifically to married heterosexual couples who wish to have a child and to unmarried women either single or living as part of a heterosexual couple. It does not refer to homosexual couples but it does indirectly forbid their access to fertility services.

According to the 2002 Law [3089/02]:

- A. the written consent of the married couple is required before the MAP procedure
- B. consent before a notary public is demanded for a single woman or a couple living in a free-union

Ireland

On the basis of equality and non-discrimination, it is proposed that the legislation will provide that assisted human reproduction services should be available to people irrespective of gender, marital status or sexual orientation subject to consideration of the welfare of any future children.

Luxembourg

Selection on the basis of a psychologist's opinion and following the recommendations formulated by the National Ethics Commission.

Malta

There is no legal framework

Netherlands

Basic principle is to have no difference in access for single or lesbian women. However, some IVF-centers apply a stricter selecting policy then others.

Norway

A change in our legislation entered into force on January 1st 2009, allowing access to MAP for lesbian couples. Single women do not have access to MAP.

Poland

There is no specific legislation on the subject. In practice only heterosexual couples are concerned.

San Marino

See comments on legal instruments.

Portugal

Any women – even being single and without any sexual relationship, and without infertility can go to a specific ART centre and ask for artificial insemination

Russian Federation

Possible for a single woman.

Slovenia

Art. 5: MAP is available to heterosexual couples living in marriage or in extra-marital relationship, which must exist at the time the procedure is performed.

<u>Spain</u>

Every woman over 18 years with full capacity to act may be a recipient or user of the techniques regulated by this Law, provided that he has given his written consent. The woman may be user or recipient of the techniques covered in this law regardless of their marital status and sexual orientation.

Sweden

As from 1/4/2016 single females gain access.

Ukraine

Possible for single women; not for persons living in homosexual couple.

United Kingdom

The Human Fertilisation & Embryology Act 1990 (HFE Act) does not prohibit treatment for same sex couples or single women

Canada

Restrictions are not placed on access to medically assisted procreation (MAP) in Canada based on sexual orientation or marital status. Human rights instruments in Canada, such as the Charter of Rights and Freedoms and human rights legislation protect generally against discrimination based on such grounds.

In addition, section 2 of the Act sets out broad principles on which the Act is based and on which future regulations will be based. One of the principles specifically referred to is the principle of non-discrimination. Section 2(e) states that:

The Parliament of Canada recognizes and declares that [....]

(e) persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status.

Israe

While IVF is not restricted, there is a restriction concerning surrogacy that is authorized only for heterosexual couples.

Medical aspects

- 2. Are there specific criteria for access to MAP?
 - Medical reasons:
 - a. Infertility
 - i. for a heterosexual couple?
 - ii. for women not living in a heterosexual couple?
 - b. Risk of transmission of a disease (please specify the risk and/or disease)
 - i. for a heterosexual couple?
 - ii. for women not living in a heterosexual couple?
 - c. Other

| Country | 2a i | 2a ii | 2b i | 2b ii | 2c | Country | 2a i | 2a ii | 2b i | 2b ii | 2c |
|-------------------------|-------------|-------------|--------------|-------|-----|------------------------|------|-------|------|-------|------|
| Albania | | | | | | Luxembourg | Yes* | Yes* | Yes* | Yes* | 1 |
| Andorra | | | | | | | | | | | |
| Armenia | | | | | | Malta | * | * | * | * | ı |
| Austria | Yes | Yes* | Yes* | Yes* | - | Republic of Moldova | | | | | |
| Azerbaijan | Yes | Yes | Yes | Yes | - | Netherlands | Yes | Yes | Yes* | Yes* | Yes* |
| Belgium | No* | No* | No* | No* | - | Norway | Yes | - | Yes* | -* | 1 |
| Bosnia & Herzegovina | Yes | No* | No | No | ı | Poland | Yes* | ı | Yes* | ı | I |
| Bulgaria | | | | | | Portugal | Yes | Yes | Yes* | - | ı |
| Croatia | Yes | Yes | Yes | Yes | - | Romania | | | | | |
| Cyprus | Yes | No* | Yes | - | - | Russian Federation | Yes | Yes | Yes | Yes | Yes* |
| Czech Republic | Yes | No | Yes* | Yes | - | Serbia | Yes | Yes | Yes | Yes | - |
| Denmark** | No* | - | No* | - | - | San Marino | -* | | | | |
| Estonia | Yes | Yes | Yes | Yes | - | Slovakia | Yes | No | Yes | - | - |
| Finland | Yes/ No* | Yes/ No* | Yes* | Yes* | - | Slovenia | Yes | - | Yes* | - | - |
| France** | Yes* | - | Yes* | - | - | Spain | Yes | Yes | Yes | Yes | - |
| Georgia | * | * | * | * | * | Sweden** | Yes* | No | Yes* | Yes* | -* |
| Germany | Yes | - | No | - | * | Switzerland | Yes | No | Yes | No | - |
| Greece | Yes* | Yes* | Yes* | No* | - | "FYROM" | Yes | -* | No* | - | - |
| Hungary | Yes* | Yes* | Yes* | Yes* | - | Turkey | Yes | No | No | No | |
| Iceland | Yes | No | No | No | * | Ukraine | Yes* | Yes* | No* | No* | - |
| Ireland | _* | _* | _* | -* | | United Kingdom | No* | No* | No* | No* | - |
| Italy | Yes | No | Yes (HIV) | No | - | Canada | * | * | * | * | - |
| Latvia | Yes | Yes | Yes* | Yes* | - | Israel | Yes | Yes | No | No | - |
| Lithuania | Yes* | No | Yes* | No | No* | | | | | | |

<u>Andorra</u>

Other: adults between 18 years and - 50 years subject to exceptions. For example, if necessary, minors could cryopreserve gametes for their own use at a later stage, in order to preserve fertility in situations of pathological procedures. Always under medical guidance.

Austria

Access permitted for heterosexual and homosexual couples, no access for single women. Access in case of high risk of transmission of a serious disease, e.g. HIV.

Belgium

There are no legal restrictions for access to medically assisted procreation. However, the law of 2007 specifies that the fertilisation centres may refuse in writing to comply with a request for MAP, either by specifying the medical reasons for the refusal or by invoking objection of conscience.

Bosnia & Herzegovina

2.a.ii. Currently no, but envisaged for single woman in the new draft legislation.

Croatia

Access to MAP have heterosexual couples and single women when there is a risk of transmission of severe hereditary disease.

Cyprus

The access to MAP for homosexual couples is not permitted for any reason.

Czech Republic

HIV/AIDS, Hepatitis etc.

Denmark

There are no restrictions in the access to medically assisted procreation neither to hetero couples or single women.

Finland

2a. Medical grounds are used as the criteria for accessing MAP in the public health care. In practice however the reasons for infertility are not always known and this has not prevented public sector clinics from providing treatment in particular to heterosexual couples (*i.e.*, provision of treatment has not always been based on a diagnosed medical condition). Another reason for not providing MAP for same-sex female couples and single women has been the lack of available donated gametes. These criteria are, however, not provided for in the legislation.

2b. MAP cannot be provided if the pregnancy would pose a substantial risk to the health of the woman or of the child due to the age or health of the woman. The donor cannot donate gametes if he has a serious hereditary disease or any communicable disease that may cause a serious illness to the woman receiving assisted fertility treatment or to the child who may be born as a result of the assisted fertility treatment.

France**

The purpose of medically assisted procreation is to rectify infertility within a couple or to avoid transmission of a particularly severe disease to the child or other member of the couple. The pathological nature of infertility must be diagnosed medically.

The bioethics draft bill envisages removing the criterion of pathological infertility in order to use MAP.

<u>Georgia</u>

2ai

LHC: <u>Yes</u> DL-RHRR: <u>Yes</u>

2aii

LHC: <u>No</u> DL-RHRR: <u>Yes</u>

2bi

LHC: Yes

"Risk of transmission of a genetic disease"

DL-RHRR: Yes

- a) "Proven likelihood of the transmission of a serious genetic disease to a naturally conceived child from a woman or man, that may result in a child's severe disability and/or premature death."
- b) "Proven likelihood that a child from natural insemination will be born with a non-genetic disease that may result in grave disability and/or premature death."

2bii

LHC: <u>No</u> DL-RHRR: <u>Yes</u>

- a) "Proven likelihood of the transmission of a serious genetic disease to a naturally conceived child from a woman or man, that may result in a child's severe disability and/or premature death."
- b) "Proven likelihood that a child from natural insemination will be born with a non-genetic disease that may result in grave disability and/or premature death."

Accordingly, the draft law of Georgia on Reproductive Health and Reproductive Rights permits access to medically assisted reproductive technologies for heterosexual couples or single women only if at least one of the conditions listed below are met:

- a) A woman and/or man of reproductive age is infertile, other alternatives available in the country for treating infertility have proved ineffective; or such treatment hasn't yet been carried out, but there is a reason to assume that it will be ineffective, as attested by a state medical institution with the proper license;
- b) There is a proven likelihood of the transmission of a serious genetic disease to a naturally conceived child from a woman or man, which may result in a child's severe disability and/or premature death;
- c) There is a proven likelihood, that a child from natural insemination will be born with a non-genetic disease, that may result in grave disability and/or premature death;
- d) A woman carries a disease due to which the pregnancy may endanger the woman's life and/or health.
- **2c-** There is one more medical criterion, but only for accessing surrogacy: existence of a disease due to which the pregnancy may endanger the woman's life and/or health.

Germany

2c

Pursuant to section 6 subs. 2 of the Tissues and Cells Regulation of the Transplantation Act, the use of sperm cells for heterologous fertilisation, as a medically assisted procreation technique requires that the sperm donor is medically assessed as suitable for sperm donation with regard to his age, state of health and medical history and that the use of the donated sperm will not pose any health risks to others. For this purpose, the donors' serum or plasma samples must be tested and found negative for HIV 1 and 2, HCV, HBV and syphilis. Furthermore, urine samples of sperm donors must be tested and found negative for chlamydia by the nucleic acid amplification technique (NAT).

Additional aspects are set out in the Model Guidelines of the German Medical Association, paragraph 5.3.1

Hungary

Medical reasons:

2ai., 2aii. Regulated in paragraphs 167, (3) and (4) of the Act, paragraphs 1 (2), (3), 1/A, 1/B, 1/C of the Decree.

2b. Risk of transmission of a disease (please specify the risk and/or disease)
Prohibited in risk of transmission of a disease endangering the viability or health of the child, and in risk of transmission of an infection

Greece

Art 4, para 1 of the 3305/05 Law refers to:

- the age limit (50 years old) of natural ability for reproduction for women participating in MAP procedures;
- the application of MAP to people under the age of 18 is permitted only in case of a serious disease that could provoke sterility in order to ensure their ability of reproduction.

The law does not provide anything for women not living in an heterosexual couple.

Art 4, para 2 refers to an obligatory examination for HIV-1&2, hepatitis B & C and syphilis before submission to MAP procedures. People with an HIV infection who wish to undergo MAP, need special permission from the National Authority of MAP.

Iceland

See Art. 3 in Act no. 55/1996 (Artificial fertilisation may only be carried out if: a) the woman undergoing the procedure has been living with a man, married or in a non-formalised

relationship, continuously for at least three years, and they have both given written consent in the presence of witnesses.

- b) the age of the couple may be deemed natural, *inter alia* with regard to the welfare of the child as he/she grows up.
- c) the mental and physical health and the social circumstances of the couple are good, and
- d) other procedures to overcome infertility have failed or are unavailable.)

Ireland

As previously mentioned, it is proposed that legislation will permit assisted human reproduction services to be available to people irrespective of gender, marital status or sexual orientation. However, in the interests of any child to be born as a result of assisted human reproduction (or any existing children in families wishing to avail of assisted human reproduction), the legislation will provide for child welfare assessments which will afford a way of assessing whether intending parents are suitable for assisted human reproduction treatment. The purpose of these assessments will be used to assess intending parents' age, health and ability to provide a stable and healthy environment for a child/children.

<u>Latvia</u>

It is not mentioned in law, but practically possible for genetically hereditary diseases, sexually Transmitted Disease (STD).

<u>Lithuania</u>

The Law on MAP of the Republic of Lithuania states that MAP can be applied to infertile couples when infertility cannot be treated by any other methods.

According to the above-mentioned Law, MAP can also be used if there is a high probability of transmitting a disease, which could cause severe disability to a future child.

Luxembourg

Biological examinations as laid down by the French Bioethics Law.

Malta**

It depends on the moral integrity and personal values of practitioners and researchers, as there is no legal framework.

Netherlands

There is a screening on sexually transmitted diseases.

2c - For women who receive a donor-oocyte there is an indicated maximum age of 45 years.

Norway

In addition to cases of infertility, assisted procreation by insemination can be offered if:

- a) the woman is a carrier of serious X-linked diseases. In such cases, the act allows that procedures for selection of sperm can be used to ensure a female offspring. Such procedures can only be accepted after thorough scientific evaluation, and must be approved by the Directorate for Health and Social affairs.
- b) the husband/spouse is affected by or carrier of a serious Mendelian disorder.

The act does not specify a right to treatment in cases where there is a risk of transmission of diseases such between the woman and her husband/spouse.

Regarding situation where one or both partners have a serious and chronic sexually transmitted infection: They may be offered MAP treatment by IVF or insemination. Where the woman is infected, an evaluation of the risk of transmitting the virus to the child must be made in each case before it is decided to proceed..

Poland

There is no specific legal provisions on the subject. In practice only heterosexual couples are concerned. Ad point b: Both partners undergo screening tests to reduce the risk of transmission of AIDS, viral hepatitis and syphilis.

Portugal

2.b.i X linked diseases

Other known genetic disorders

Russian Federation

With regard to artificial insemination of a single woman with the donated sperm, Regulations of the Ministry of Health stipulate that absence of a sexual partner is an indication to MAP.

San Marino

See general comment on relevant legal instrument.

Slovenia

Risk of transmission of serious genetically determined disease (Art. 5).

Sweder

- a.i. The couple must have attempted natural conception for a reasonable time, unless inapplicable.
- b. i,ii. The medical condition of the parents may be assessed (including parents' age, if life expectancy considering illnesses is above 18 yrs, the ability to give the child good living conditions; an assessment in the child's best interest)

c. Other

When donated gametes are utilized, the couple or the single female will be assessed regarding medical, social and economic conditions. If the couple/female are deemed unfit they may be denied treatment, this decision can be appealed to Rättsliga Rådet (a Legal Council at the National Board of Health and Welfare). Even when a couple use their own gametes there is an option for the treating clinic to deny treatment if it is considered that it may not be in the child's interest for medical reasons.

The female has to be "fertile" by biological age, normally an age limit of 40 is applied. If the oocytes are not qualitative or quantitative she may however be denied treatment at a younger age.

FYROM

There is not a law or specific articles in the healthcare law addressing MAP or people who are not living in heterosexual couple.

Ukraine

Risk of transmission is possible if donors have not gone through medical examination.

United Kingdom

Provision of treatment on the National Health Service (NHS) varies across the UK with different local clinical commissioning groups (CCGs) or health boards having differing levels of provision and different eligibility criteria. The National Institute of Clinical Health and Excellence (NICE) is the NHS body who developed the overarching guidelines which CCGs then apply locally. Guidelines can be viewed here: https://www.nice.org.uk/guidance/cg156. Private fee-paying (non-National Health Service) patients can have treatment for purely non-medical reasons if they wish.

As the UK's regulator for assisted reproduction, the HFEA requires licensed fertility clinics to follow screening requirements to avoid the transmission of diseases. Donors have to be screened for infectious diseases such as HIV, Hepatitis B and C and Cytomegalovirus (CMV). Among the criteria to be considered is the patient's age, health and ability to provide for the needs of a child/children. Further information on screening requirements can be viewed in the HFEA's code of practice: http://www.hfea.gov.uk/498.html

Clinics ultimately must decide fairly whether to offer or refuse treatment. Further information on guidance to treating people fairly when receiving fertility treatment is included in the HFEA code of practice: https://www.hfea.gov.uk/media/2793/2019-01-03-code-of-practice-9th-edition-v2.pdf

Canada

The Act does not address access to MAP for medical reasons. Therefore, fertility clinics and practitioners are able to formulate their own policies with respect to accepting patients based on certain medical criteria. For example, a fertility clinic may choose not to accept a heterosexual couple as patients unless they have tried unsuccessfully to conceive for one year.

With respect to access to MAP for those who risk transmitting a disease, there is currently only one facility in Canada that offers pre-implantation genetic diagnosis services. Other fertility clinics offer genetic counseling services. Again, fertility clinics and practitioners are

able to formulate their own policies with respect to accepting patients who are at risk of transmitting diseases to their offspring, as long as the principles of non-discrimination are respected.

Financial aspects

3. Are MAP procedures covered by the social security system? Please explain why (e.g. infertility considered as a disease).

| Country | Reply | Country | Reply |
|-------------------------|-------|-----------------------|---------|
| Albania | | | |
| Andorra | | Luxembourg | Yes |
| Armenia | | Malta | No* |
| Austria | * | Republic of Moldova | |
| Azerbaijan | No | Netherlands* | Yes* |
| Belgium | Yes* | Norway | Yes* |
| Bosnia & Herzegovina | Yes* | Poland | No |
| Bulgaria | | Portugal | Yes* |
| Croatia | Yes | Romania | |
| Cyprus | No* | Russian Federation | Yes* |
| Czech Republic | Yes | San Marino | _* |
| Denmark | Yes* | Serbia | Yes |
| Estonia** | Yes* | Slovakia | Yes* |
| Finland | Yes* | Slovenia | Yes* |
| France** | Yes* | Spain | Yes* |
| Georgia | No* | Sweden | Yes* |
| Germany | Yes* | Switzerland | No/Yes* |
| Greece | Yes* | "FYROM" | No* |
| Hungary | Yes* | Turkey | Yes |
| Iceland | Yes* | Ukraine | No* |
| Ireland | No* | United Kingdom | Yes* |
| Italy | No | Canada | * |
| Latvia | No* | Israel | Yes* |
| Lithuania** | Yes* | | |

Austria

Unfulfilled desire to have children is not considered as a disease.

A fund is established to cover 70% of costs of IVF – treatments under specific conditions.

Belgium

The patient is not liable for the costs arising from all the *laboratory work* entailed in IVF/ICSI insemination of eggs if she is not more than 42 years old, with a maximum of 6 attempts per woman (Royal Decree of 25 April 2002 concerning the setting and liquidation of the budget for the financial resources of hospitals, Art. 74bis). The thinking behind this rule is that after the age of 43, MAP has very little chance of success.

Since 2008 (Royal Decree of 6 October 2008 introducing a flat-rate reimbursement for female infertility treatments), sickness and invalidity insurance has also provided a flat-rate reimbursement for *pharmaceutical specialities* prescribed by a gynaecologist and delivered in a hospital, which are used in the context of intra-uterine insemination or ovarian stimulation. The woman must be not more than 42 years old, however, and reimbursement is available for

a maximum of 6 cycles/completed treatments per woman. Patients have to pay a share of the cost.

As regards *other services* in connection with MAP, these are partially covered by sickness and invalidity insurance (e.g. embryo implantation after in vitro fertilisation): the patient has to pay a share of the costs.

Bosnia & Herzegovina

Currently only for 2 procedures in the entities Federation BiH, Republika Srpska and Brcko district.

Croatia

Infertility is defined as a disease.

Cyprus

The Ministry of Finance covers the cost of MAP procedures.

Czech Republic

Infertility is defined as a disease.

Denmark

Regional must provide cost-free treatment for MAP to single women who do not have children, and couples who do not have children together.

Estonia**

Estonian Health Insurance Fund covers 6 consecutive attempts for women until age 40. In general MAP is allowed for women until age 50. Reason is not defined by law or other legislative documents.

Finland

Public health services include MAP procedures. Pursuant to the Health Insurance Act (sairausvakuutuslaki; 1224/2004), health insurance covers the cost of necessary medical care when infertility is caused by an illness. Infertility is in addition paralleled to illness in cases of permanent relationships where the pregnancy does not start within one year. Also men are covered.

France**

Medically assisted procreation is considered to be a health care activity. The draft bill currently under discussion provides for the possibility of reimbursement of MAP by social security under the same conditions for single women, female couples and heterosexual couples.

Hungary

Hungarian legal regulation considers infertility a pathological condition attaining families or even single women desiring to be mother. The legal model of the treatment of MAP is the same as that of any other disease. (Act, Decree and Decree 49/1997 of the Minister of Welfare on Medical interventions against infertility to be financed by the social security system).

Georgia

Due to the general difficult economic conditions in Georgia, the Health and Social Security System is not able to cover such high technology procedures as MAP.

Germany

MAP is a medical therapy under section 27a Book V of the Social Code.

The medical services covered by the statutory health insurance also include medical interventions aimed to induce a pregnancy. MAP measures must be medically diagnosed as necessary and have reasonable chances of success.

The Statutory Health Insurance Modernisation Act [GKV-Modernisierungsgesetz] reasonably restricted the entitlement to MAP measures from 1 January 2004. 50% of the costs are covered by the health insurance fund, so that the insured equally share in the costs of MAP interventions with a co-payment of 50%.

To reduce the financial burden caused by the 2004 cutback in costs covered by the statutory health insurance fund, in 2012 the Federal Ministry for Family Affairs launched the federal initiative "Hilfe und Unterstützung bei ungewollter Kinderlosigkeit" (assistance and support for involuntary childlessness). The funds are paid from both the federal budget and the budget of the Länder in which the couples concerned have their principal residence. Currently, six of the sixteen Länder participate in the initiative. Federal funding is generally provided for the first four treatment cycles of in-vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI). Couples can be reimbursed up to 25 per cent of the share they have to pay in addition to the costs covered by the health insurance fund.

Until 2015, only married couples were entitled to additional federal financial assistance. Today, also unmarried couples living in a non-marital long-term relationship can receive federal financial assistance under the amended federal guidelines on financial assistance for assisted reproduction procedures (Richtlinie über die Gewährung von Zuwendungen zur Förderung von Maßnahmen der assistierten Reproduktion), which took effect on 7 January 2016. However, pursuant to section 27a Book V of the Social Code, entitlement to benefits from the statutory health insurance fund is still restricted to married couples only.

Greece

Article 28, para 1 of Law 3305/05 refers to the reimbursement of MAP procedures by Social Security, the presuppositions of which will be defined by a presidential decree to be published. The same presidential decree will assess the conditions under which reimbursement by the Social Welfare is given to people who wish to participate in MAP procedures and who are not insured. Therefore, as far as security coverage is concerned, the situation in Greece remains variable, depending on different social security funds. The Opinion proposed for full coverage of all necessary medication.

Iceland

Partially covered.

Ireland

Although in vitro fertilisation (IVF) treatment is not provided by the Irish public health service, there is some support available in that patients who access IVF treatment privately may claim tax relief on the costs involved under the tax relief for medical expenses scheme. In addition, a defined list of fertility medicines needed for fertility treatment is covered under the High Tech Scheme administered by the Health Service Executive (HSE). Medicines covered by the High Tech Scheme must be prescribed by a consultant/specialist and approved by HSE 'High Tech Liaison Officers'. The cost of the medicines is then covered, as appropriate, under the Medical Card or Drugs Payment Scheme.

Latvia

Due to the small budget for social security.

Lithuania**

Infertility is defined as a disease thus MAP procedures are compensated for a limited extent (please see the answers to the question 5).

Malta

Diagnostic Tests for infertility are carried out for free under the National Health Scheme, however, the treatment procedures are not provided for free.

People have access to pharmacological treatment for free for a number of diseases under the National Health Scheme. These diseases are listed under the Social Security Act, and infertility is not one of them.

Netherlands

Yes, but partly. In case of IVF, there is a maximum of three attempts.

Norway

MAP procedures are covered by the National Health care system and by co-payments. The (outpatient) clinic where the MAP procedure is conducted is financed as follows:

- Fee-for-service reimbursement from the National Insurance Scheme based on the treatments of IVF and intracytoplasmic sperm injection (ICSI) procedures
- en bloc subsidies from the state

 Co-payments from the patients, the couple pays maximum NOK 16700 to cover some medicines and treatment costs for IVF/ICSI. The couples are usually offered three treatment cycles (three IVF or ICSI procedures, or a combination).

Portugal

Previously, infertility was considered as a disease, now, since July 2016, according to what the law calls principle of equality, every women, single or married, with or without infertility can ask to be inseminated

Russian Federation

Infertility is considered as a disease. Social security covers extra-corporal fertilisation only (but neither gametes donation nor surrogacy).

San Marino

Infertility is followed free of charge, the healthcare system covering 2 pharmacological treatment cycles and the pre and post implantation. The gametes extraction techniques, fertilisation, implantation and embryo storage at Italian specialised structures are the responsibility of the couple as well as any subsequent treatment cycles to the two provided free of charge.

Slovakia

Infertility is considered as a disease.

Slovenia

Indeed, infertility is considered a medical condition of the couple.

Spain

Where permitted by law: infertility, therapeutic or preventive purposes.

Sweden

This may differ between counties but normally MAP is covered up to a limited number of attempts, presently most state owned/contracted clinics offer three attempts by national recommendation (by the Swedish Association of Local Authorities and Regions, SKL). MAP is considered part of health care.

Switzerland

IUI YES, IVF NO. Cost effectiveness of IVF is - until today - considered as insufficient

<u>"FYROM"</u>

MAP is not incorporated in the social security system. The drugs for infertility may be covered (80 %) only if patient is treated by the hospital facilities.

<u>Ukraine</u>

First step is made to cover one cycle in case of bilateral tubectomy.

United Kingdom

Infertility is classified as a medical condition.

Canada

In general, MAP procedures are not covered by the health care system. In Canada, the recipient pays for 99 percent of all assisted human reproduction procedures received. One exception is in the province of Ontario, where a maximum of three cycles of in vitro fertilization treatment is covered where both of the patient's fallopian tubes are blocked.

<u>Israel</u>

Infertility is considered as a disease.

4. Are there specific criteria for such coverage (e.g. infertility, age limit)?

| Country | Reply | Country | Reply |
|-------------------------|-------|-----------------------|-------|
| Albania | | | |
| Andorra | | | |
| Armenia | | Luxembourg | Yes* |
| Austria | * | Malta | - |
| Azerbaijan | No | Republic of Moldova | - |
| Belgium | Yes* | Netherlands* | Yes* |
| Bosnia & Herzegovina | Yes* | Norway | Yes* |
| Bulgaria | | Poland | - |
| Croatia | Yes* | Portugal | Yes* |
| Cyprus | Yes* | Romania | |
| Czech Republic | Yes* | Russian Federation | Yes* |
| Denmark | Yes* | San Marino | No |
| Estonia** | Yes* | Serbia | Yes* |
| Finland | Yes* | Slovakia | Yes |
| France** | Yes* | Slovenia | Yes* |
| Georgia | - | Spain | Yes* |
| Germany | Yes* | Sweden | * |
| Greece | Yes* | Switzerland | - |
| Hungary | Yes* | "FYROM" | No |
| Iceland | Yes* | Turkey | Yes* |
| Ireland* | -* | Ukraine | Yes* |
| Italy | No | United Kingdom | Yes* |
| Latvia | No | Canada | * |
| Lithuania** | Yes* | Israel | Yes* |

Austria

(See answer to question 3.)

Specific criteria for coverage are:

- male sterility and/or female sterility (occluded fallopian tubes, endometriosis, polycystic ovary syndrome (PCO);
- age of intended mother up to 40 years, age of the partner up to 50 years.

Belgium

Age of the woman = 42 maximum because very little chance of success after that.

Bosnia & Herzegovina

Infertility, age limitation (37 in FBIH, 41 in RS).

Croatia

Procedures are covered for infertile couples (infertility is considered a disease), for women up to 42 years (natural generative age, estimated by the professional society).,

Cyprus

Specific criteria for such coverage are: (1) infertility (2) for women under 40 years old.

Czech Republic

Age limit for the woman 49 years

Denmark

Women over 45 year of age cannot receive treatment.

Estonia**

Specific criteria – age limit 40.

Finland

Pursuant to the practice instructions of the Socio-medical Advisory Board of the Social Insurance Institution of Finland, MAP-procedures are available within the public health care to women until the age of 40. Also women over 40 years are treated if the prognosis is good. The costs are reimbursed by the health insurance scheme until the age of 43 years. In case of older women, the health insurance coverage is assessed on a case-by-case basis in the light of the medical data of the woman concerned.

France**

The pathological nature of infertility must be diagnosed medically.

The man and woman constituting the couple must be of reproductive age.

The health insurance system will only cover the costs of female patients aged under 43 on the day of egg retrieval.

The draft bill envisages removing the criterion of infertility and provides for the possibility of reimbursement of MAP by social security under the same conditions for single women, female couples and heterosexual couples.

Hungary

Infertility is the condition for the coverage of MAP. Age can only be considered in respect of the health condition preventing fertility.

Decree 49/1997 specifies more closely the conditions to be applied.

Germany

The criteria included in section 27a of Book V of the Social Code:

Coverage of part of the costs by the statutory health insurance funds is subject to the following requirements:

- the measures must be medically diagnosed as necessary
- according to medical diagnosis, the intervention must be reasonably likely to induce a pregnancy
- the procedure may be performed up to three times
- only married couples are eligible (non-married couples are not)
- only the spouses' egg and sperm cells may be used (homologous system)
- prior to treatment, the spouses must have themselves thoroughly informed about the medical and psychosocial consequences and risks involved by a physician other than the one who will perform the treatment
- MAP may only be performed by physicians or facilities that are suitably qualified and have obtained an appropriate licence from the authority responsible under the law of the federal *Land*

Any method other than homologous fertilisation is excluded from the mandatory package of benefits and services of the statutory health insurance system.

The restriction of eligibility to married couples is in accordance with the Constitution (cf. BVerfGE 117, 316). Methods other than homologous fertilisation are excluded from the mandatory package of services.

Eligibility is subject to age limits of between 25 and 40 years for women and between 25 and 50 years for men.

Although unmarried heterosexual couples are not entitled to benefits from the statutory health insurance fund pursuant to section 27a of Book V of the Social Code, they can receive the voluntary financial assistance offered through the federal initiative "Hilfe und Unterstützung bei ungewollter Kinderlosigkeit".

Greece

The presidential decree which will be published according to the provisions of Law 3305 will cover terms, conditions and procedures for financial coverage by social security organisations.

Iceland

The proportion of the payment covered by the social security system differs according to how many times treatment has been undertaken.

Ireland

Assisted human reproduction is provided for in the private sector and at present there are no standard limits relating to age or infertility. However, most providers of assisted human reproduction services adhere to the guidelines produced by the Irish Fertility Society.

Lithuania**

Specific criteria for coverage are age limit of woman (under 42 years), infertility of the couple or a needed for PGD due to high probability of transmitting a disease, which could cause severe disability to a future child.

Luxembourg

Age limit of woman – 40 years old.

Netherlands

Age limit of woman – 42 years old.

Norway

All couples that are offered MAP through the national health care system have a right to partial coverage of the treatment. Whether treatment will be offered or not depends on the following:

As a first step in the process, the couple will consult their family physician. Based on an medical and psychosocial evaluation of the couple the physician will decide whether to recommend the couple to one of the clinics offering MAP.

Many clinics have established guidelines for evaluation of couples asking for medically assisted procreation.

In practise, private clinics may offer treatment for women over 40 whereas the clinics financed by the national healthcare system (most often hospital clinics) may not be able to prioritise women over 40 (mainly due to low cost-effectiveness of the treatment).

According to the Act on Biotechnology, a clinic offering MAP needs authorisation or approval from the Directorate for Health and Social Affairs.

<u>Portuga</u>

There is only a lower age limit 18 years (n°2, art 6°, law 32/2006), in all the country 40 years in the NHS.

Russian Federation

Infertility only.

Serbia

Age limit for treatment of infertility with BMAF is 40 years

Slovenia

The criteria are the same as those entitling the couple to MAP. These include infertility not treatable in other ways, age appropriate for pregnancy (the upper age limit for the woman is 43 years) and parenthood, the need to avoid transmission of a serious genetic disorder.

Spain

Medically assisted procreation (MAP) is applied in the National Health System to people who meet the following criteria or situations including:

- 1. Women will be over 18 and under 40 and men over 18 and under 55 years at the time the study began sterility.
- 2. People without any child, prior and healthy. In case of couples, no common, prior and healthy child.
- 3. The woman did not present any pathology in which pregnancy may have caused a serious and uncontrollable risk, both for their health and for their potential offspring.

Sweden

By national recommendations: If the couple/female is approved by above mentioned criteria she will receive up to three attempts. Females above 40 will however normally not be approved for treatment, unless embryos were frozen before she turned 40, in which case the

embryos may be used before she turns 45. This applies regardless of financial coverage. The other parent must not be above 56 years old.

Turkey

Married, infertile couples, older than 23, younger than 40 years old can benefit from assisted reproduction (IVF) techniques

<u>Ukraine</u>

- 1. Only tubal factor of infertility.
- 2. Age up 35 years.

United Kingdom

As public funding for medical services has to cover priorities within a set budget, there are conditions for access to National Health Service (NHS) funded treatment. The UK's National Institute for Clinical Excellence (NICE) has provided guidance on access to NHS funded treatment which can be found on this page: https://www.nice.org.uk/guidance/cg156

<u>Canada</u>

See answer to question 3.

Israe

Possible until the age of 45 with autologous oocytes.

5. Is the financial coverage limited to a number of MAP procedures (e.g. three IVF procedures only)?

| Country | Reply | Country | Reply |
|-------------------------|-------|------------------------|-------|
| Albania | | Luxembourg | Yes* |
| Andorra | | | |
| Armenia | | Malta | - |
| Austria | Yes* | Republic of Moldova | |
| Azerbaijan | Yes | Netherlands | Yes* |
| Belgium | Yes* | Norway | Yes* |
| Bosnia & Herzegovina | Yes* | Poland | - |
| Bulgaria | | Portugal | Yes* |
| Croatia | Yes* | Romania | |
| Cyprus | Yes* | Russian Federation | No |
| Czech Republic | Yes* | San Marino | Yes* |
| Denmark** | Yes* | Serbia | Yes* |
| Estonia** | Yes* | Slovakia | Yes* |
| Finland | Yes* | Slovenia | Yes* |
| France | Yes* | Spain | Yes* |
| Georgia | -* | Sweden | Yes* |
| Germany | Yes* | Switzerland | Yes* |
| Greece | Yes* | "FYROM" | No |
| Hungary | Yes* | Turkey | No |
| Iceland | Yes* | Ukraine | Yes* |
| Ireland | No | United Kingdom | No* |
| Italy | No* | Canada | * |
| Latvia | No | Israel | No* |
| Lithuania** | Yes* | | |

Austria

Limitation to four IVF procedures; if a pregnancy is achieved further four IVF procedures are possible.

Belgium

Maximum of six attempts.

Bosnia & Herzegovina

2 procedures

Croatia

Social health insurance covers up to 4 intrauterine insemination procedures (IUI) and up to 6 in vitro procedures (IVF)

Cyprus

The financial coverage is limited to only one (1) MAP procedure.

Czech Republic

6 IUI cycles /year, 4 IVF cycles/life.

Denmark

Practice: 3 procedures with IVF and more if there are one or more spare, frozen embryos from the woman.

Estonia**

Limits are set by law - 6 consecutive procedures are covered by EHIF

Finland

The financial coverage has not been limited by law. The number of MAP procedures has however been limited to three attempts in the practice of the Social Insurance Institution of Finland, because according to statistics, the prospect of a successful procedure is known to decrease thereafter.

Infertility related to a decrease in the amount of gametes caused by aging is not considered an illness and is thus not covered as necessary medical care by the health insurance. MAP procedures are usually not covered after sterilization either. Possible costs borne by a cell donor are not covered, because they are unrelated to the treatment of the donor's disease.

The insurance coverage of MAP procedures for an applicant over 43-years of age is decided upon on a case-by-case basis. An application for reimbursement is made with the Social Insurance Institution of Finland for both the medicines and the procedure itself. A statement by the doctor providing treatment must be attached to the application.

France

The health insurance system will cover six inseminations and four complete cycles, i.e. concluded by embryo transfer. Any IVF cycle broken off before embryo transfer, irrespective of the stage at which it is abandoned, will not be counted by the health insurance system. Reimbursement is subject to a preliminary agreement procedure.

Should pregnancy and delivery occur, the count restarts from zero, and coverage is provided for four new attempts. This does not apply to miscarriages or extrauterine pregnancies.

<u>Hungary</u>

Interventions ending with embryo implantation can be covered five times maximum for the same patient.

<u>Georgia</u>

The same reasons as question 3 connected with economic situation in the country.

Germany

As of 1 January 2004, the health care reform introduced a reasonable restriction to the entitlement to benefits and services. Since then, only three instead of four attempts to induce

a pregnancy have been partially covered by the health insurance funds. The payment of expenses by the health insurance funds has been limited to 50% of the costs approved along with the treatment schedule.

Greece

In the Opinion submitted by the National Authority it was proposed to cover 4 IVF/GIFT/ZIFT attempts. The Opinion also included a variety of medical criteria and age limits. As far as sperm injection is concerned the Opinion proposed for financial coverage of 6 attempts.

Iceland

For couples without a child together coverage for first treatment approx. 50%

For second to fourth treatments approx. 70%. No coverage for further treatments.

For couples with one child. Coverage for first to fourth treatment approx. 20%. No coverage for further treatments. No coverage for couples with more than one child.

Italy

It is not possible to produce more than 3 embryos to transfer to the uterus for each attempt except where there are obvious problems of development.

Lithuania**

No more than two treatment cycles per couple are compensated from the National Health Insurance Fund.

Luxembourg

Four attempts.

Netherlands

See answer to question 3.

Norway

Financial coverage is limited to three MAP procedures (three IVF or ICSI procedures - or a combination, where a procedure includes the retrieval of ova). Implantation of stored embryos (FER) is not counted as a "MAP procedure".

Portuga

3 cycles for IVF at the National Health Service

At the moment it is not clear how many artificial inseminations can be done in single or homosexual women in NHS.

San Marino

See comment to question 3.

Serbia

MAP procedures are covered only for 3 IVF procedures.

Slovakia

Only two.

Slovenia

Up to four IVF procedures are covered. The rate of pregnancies achieved is among the highest in Europe, in spite of the fact that since 1999, a maximum of two embryos is transferred in a single MAP procedure.

Spain

The financial coverage limited to:

Three IVF procedures only

Artificial insemination with sperm from the couple: maximum number of cycles, four Artificial insemination with donor gamete: maximum number of cycles, six.

Sweder

Up to three attempts are normally covered.

Switzerland

IUI: 3 cycles

<u>Ukraine</u>

Only one IVF procedure.

United Kingdom

Although guidelines exist on access to NHS funded treatment for IVF and IUI, it is for local clinical commissioning groups (CCGs) or health boards to decide the appropriate health care services to fund for their communities. Patients who pay for their own treatment are not limited in the number of procedures they can have.

Canada

(See answer to question 3)

<u>Israel</u>

Fully covered until achievement of two children.

Sperm/oocyte/embryo donation

6. Are donation of the following permitted in your country?

- a. Sperm
- b. Oocytes
- c. Embryos

| Country | а | b | С | Country | а | b | С |
|-------------------------|------|------|------|------------------------|------|------|------|
| Albania | | | | Luxembourg | Yes | Yes | No |
| Andorra | Yes | - | Yes | | | | |
| Armenia | | | | Malta | Yes* | Yes* | Yes* |
| Austria | Yes | Yes | No | Republic of Moldova | | | |
| Azerbaijan | Yes | Yes | No | Netherlands | Yes | Yes | Yes |
| Belgium | Yes | Yes | Yes | Norway | Yes | No | No |
| Bosnia & Herzegovina | No | No | No | Poland | Yes* | Yes* | Yes* |
| Bulgaria | | | | Portugal | Yes* | Yes* | Yes |
| Croatia | Yes | Yes | Yes | Romania | | | |
| Cyprus | Yes* | - | - | Russian Federation | Yes | Yes | Yes |
| Czech Republic | Yes* | Yes* | Yes* | San Marino | -* | | |
| Denmark** | Yes* | Yes* | Yes* | Serbia | Yes | Yes | Yes |
| Estonia | Yes | Yes | Yes | Slovakia | Yes | Yes | Yes |
| Finland | Yes | Yes | Yes | Slovenia | Yes | Yes | No* |
| France** | Yes | Yes | Yes | Spain | Yes | Yes | Yes |
| Georgia | Yes* | Yes* | Yes* | Sweden | Yes | Yes | No* |
| Germany | Yes | No | * | Switzerland | Yes | No | No |
| Greece | Yes* | Yes* | Yes* | "FYROM" | No* | No* | No* |
| Hungary | Yes | Yes | Yes | Turkey | No | No | No |
| Iceland | Yes* | Yes* | No* | Ukraine | Yes* | Yes* | Yes* |
| Ireland | Yes* | Yes* | Yes* | United Kingdom | Yes | Yes | Yes |
| Italy | Yes | Yes | No | Canada | Yes* | Yes* | Yes* |
| Latvia | Yes | Yes | Yes | Israel | Yes | Yes | No |
| Lithuania** | Yes | Yes | Yes | | | | |

Cyprus

Sperm donation is being done in practice but not under the provisions of any law. For (b) and (c) the situation is unknown as there are no cases referred to.

Czech Republic

Sperm (oocytes) embryos can be donated only if the person concerned agrees with it.

Denmark

In general, all men can donate sperm and all women can donate oocytes if this does not involve any known serious genetic or infectious risk. The tissue establishment in charge of testing, processing, preservation, storage or distribution of human tissues and cells has the responsibility to ensure the quality of sperm and oocytes. Donation of embryo is only permitted for research purposes, not for assisted reproduction.

France**

Double gamete donation is however prohibited (but could be authorized within the framework of the bioethics bill currently under discussion in the Parliament).

Georgia

Both, the Law on Health Care and draft Law on Reproductive Health and Reproductive Rights in principle permit donation of gametes and embryo.

However, the Law on Health Care does not include specific provisions on this issue. It includes only a general provision saying donor's gamete(s) or embryo could be used for MAP. The draft Law on Reproductive Health and Reproductive Rights is more specific. It includes a separate chapter on gamete donation, which defines conditions and procedures for gamete donation.

Germany

Embryo donation per se is not regulated by law. However, the Embryo Protection Act provides that an oocyte may only be artificially fertilised for the purpose of bringing about a pregnancy in the same woman from whom the oocyte has been obtained (section 1 subs. 1 no. 2 of the Embryo Protection Act) and that it is prohibited to remove an embryo from a woman before its nidation is completed, in order to transfer it to another woman (section 1 subs. 1 no. 6 Embryo Protection Act). In addition, the Act incorporates provisions aimed to prevent the creation of supernumerary embryos in the course of artificial fertilisation (especially the ban on the artificial fertilisation of more oocytes than can be inserted into a woman within one cycle - section 1 subs. 1 no. 5 Embryo Protection Act). Consequently, permissible embryo donation is only conceivable in exceptional instances where an artificially created embryo can unexpectedly no longer be transferred to the woman from whom the oocyte originated.

Iceland

See http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/686

Ireland

Under the Children and Family Relationships Act 2015, gamete and embryo donation are permitted on a non-anonymous basis. In addition, this legislation provides for the establishment of a National Donor-Conceived Person Register, which will allow donor-conceived children to access certain information regarding the gamete/embryo donor involved in procedures leading to their conception. It is intended that the proposed legislation pertaining to assisted human reproduction will deal with the broader issues relating to donor conception (e.g. age limits, screening, storage periods, the avoidance of consanguinity and donation for research purposes).

Lithuania**

The Law on Medically Assisted Procreation of the Republic of Lithuania (2016-09-14 No. XII-2608) legalises donation of reproductive cells when one of the spouses or partners have damaged or insufficient reproductive cells which cannot be used for assisted fertilisation, as well as in cases when they have a high risk of transmitting a disease likely to cause significant disability. The Law also allows embryo donation. According to para. 8 of Art. 3, donation of embryos stored in the germ cell bank is possible if the spouses (partners) reject the embryo in writing. Such refusal is not possible before the expiry of two years after the beginning of MAP procedures.

Malta

No legal framework.

Poland

There are no legal provisions on the subject.

Clinics' internal regulations define the specific medical criteria applicable to donors. Some questions are covered by the Opinion of the Polish Association of Obstetricians.

Portugal

Sperm and oocyte donation are anonymous

San Marino

See comment on relevant legal instrument

Slovenia

Embryo donation as well as MAP with both gametes donated is not allowed (Art. 13, Art. 7), on the basis of the principle that the child born with the MAP procedure should be genetically related to at least one of the parents.

Sweden

Sperm and oocyte donation are allowed. Embryo donation will be allowed from the 1st January 2019, if a couple or a single female consent in writing, they have children of their own, one of them is genetically linked to the embryo, and they are informed of the consequence of the donation; that their children may have genetic siblings in another family and will have the right to know of their origin. Any third party donor must consent specifically to embryo donation only if they donated before the law was amended, i.e. before the 1st January 2019.

"FYROM"

There is no legal regulation in the country therefore no gamete banks aiming to this are functioning.

Ukraine

It is possible to make cryoembryotransfer.

Greece

Donation of gametes (sperm and oocytes) and fertilized ova (only supernumerary fertilized ova) is allowed only with consent of the donors.

Canada

Altruistic donations of sperm, oocyte and *in vitro* embryos are permitted in Canada. Pursuant to section 7 of the Act, the purchase of sperm or eggs from a donor is prohibited. In addition, the purchase or sale of an in vitro embryo is prohibited. Altruistic donation of sperm, eggs and in vitro embryos is in keeping with the Canadian tradition and practice whereby human organs, tissues, and blood are donated, rather than sold or purchased, for the use of those in need.

7. Are there specific compensation arrangements for such donation(s) (e.g. financial compensation, reduced fees for a MAP procedure in the case of oocyte donation)?

| Country | Reply | Country | Reply |
|-------------------------|-------|-----------------------|-------|
| Albania | | Luxembourg | No |
| Andorra | * | | |
| Armenia | | Malta | * |
| Austria | No | Republic of Moldova | |
| Azerbaijan | Yes | Netherlands* | No* |
| Belgium | No* | Norway | Yes* |
| Bosnia & Herzegovina | N/A | Poland | No* |
| Bulgaria | | Portugal | Yes |
| Croatia | No | Romania | |
| Cyprus | * | Russian Federation | Yes* |
| Czech Republic | Yes* | San Marino | - |
| Denmark** | No* | Serbia | No* |
| Estonia | Yes | Slovakia | No |
| Finland | Yes* | Slovenia | No* |
| France | No* | Spain | Yes* |
| Georgia | No* | Sweden | - |
| Germany | No | Switzerland | No |
| Greece | Yes* | "FYROM" | No |
| Hungary | Yes* | Turkey | No |
| Iceland | No | Ukraine | No |
| Ireland | Yes* | United Kingdom | Yes* |
| Italy | No | Canada | Yes* |
| Latvia | No | Israel | No |
| Lithuania** | No* | | • |

Andorra

Donation is never in its nature profitable or commercial. Nevertheless, financial compensation is possible strictly in order to compensate the physical inconveniences as well as work and travel expenses resulting from the donation. Such compensation cannot constitute an economic incentive. The conditions [for its allocation] must be set through regulation.

<u>Belgium</u>

The 2007 Act states that only donations of supernumerary embryos and gametes which are made free of charge are lawful.

The Act does allow the King, however, to specify an allowance to cover the travel expenses or loss of earnings of the person from whom the gametes are being obtained. This allowance can also cover the hospital fees arising from the retrieval of oocytes from the donor. So far, however, no decrees have been issued to this effect.

In practice, all costs arising from medical examinations and procedures during treatment are borne by the recipient. Sometimes, too, the fertility centre requires the woman receiving the oocytes to pay the donor an "allowance" while sperm donors receive a small amount of compensation for each usable sample.

<u>Croatia</u>

Only direct costs are allowed to be reimbursed (such as: traveling costs)

Cyprus

It is not possible to say whether there are specific compensation arrangements for such donations as it is not a legally regulated issue.

Czech Republic

Financial compensation of expenses and loss of income.

Denmark

It is not allowed to sell or otherwise assist in the sale of unfertilized or fertilized oocytes. The compensation to the donor for donation of oocytes is, therefore limited to expenses actually incurred and disadvantages that are directly related to the donation.

Finland

The expenses borne by the patient, a possible loss of income and any other inconvenience caused by the MAP may be compensated. For ovum donation, a maximum amount of 250 euros may be reimbursed due to inconvenience. Other types of remunerations and payments are forbidden.

France

No payment in any form may be made to a person on whom parts of his or her bodyare removed of body products collected.

The full costs associated with removal or collection are nevertheless covered by the health care institution responsible for carrying it out.

The health care institution conducting removal accordingly reimburses the donor on production of the necessary supporting documents for transport and accommodation expenses (travel for tests and treatment before or after removal or collection and travel to allow the donor to provide consent). Accommodation expenses other than donor hospitalisation are covered on the basis of actual costs incurred. The health care institution carrying out removal will cover the cost of any loss of income to the donor (where relevant). The health care institution carrying out the removal or collection covers the costs of tests or treatments requested for removal purposes, all hospitalisation costs and the costs of the follow-up and medical care given to the donor owing to the removal he or she has undergone.

<u>Hungary</u>

Financial rewards are explicitly prohibited. Compensation for travel costs, administrative burdens and loss of earnings are legal under conditions (Act § 170 (3))

Georgia

LHC: No

DL-RHRR: <u>No;</u> According to the article 20 of DR-RHRR "there is no reimbursement for gamete donation. A donor shall be reimbursed for time spent and other expenses incurred by donorship" (e.g. time, transport, absence from office, etc.).

Greece

According to Law 3305/05, (Art 8, para 1) "Reward or compensation for donation of gametes and fertilized ova are prohibited. However, medical, nursing or laboratory expenses travel and accommodation expenses as well as compensation for absence from work are possible."

The National Authority for Medically Assisted Reproduction with a subsequent Decision (Decision No 36, State Journal 670 B' 16.4.2008) provides for compensation of medical, laboratory and nursing expenses occurring before and after donation. It also provides for accommodation and transportation expenses. This amount must not exceed 200E for sperm donation and 600 E for oocyte donation. Compensation is also provided for absence from work.

Ireland

Under the Children and Family Relationships Act 2015, commercial gamete and embryo donation is prohibited. Gamete and Embryo donation may only operate on an altruistic basis and the reimbursement of reasonable expenses incurred as part of the donation process will be permitted. Reasonable expenses, for the purposes of the Act means: travel costs, medical expenses and any legal or counselling costs incurred by the donor.

Lithuania**

According to the Law on MAP of the Republic of Lithuania, human gametes and embryos cannot be the object of commercial agreement.

Malta

No legal framework.

Netherlands

Compensations are legally limited to only compensation of costs made for the donation.

Norway

There will be a small compensation for donation of sperm that also covers travel expenses. In addition, coverage of documented travel expenses that exceeds the standard compensation may be covered, but only up to a certain limit.

The Norwegian legislation allows the use of donor sperm both for insemination and for IVF/ICSI. Oocyte donation is not allowed.

Poland

There are no legal provisions on the subject.

The Opinion of the Polish Association of Obstetricians provides for the lump-sum compensation of donors of genetic material for the expenses incurred.

Russian Federation

Sperm donors are compensated. With regard to compensation for oocyte or embryo donation, the situation is not quite clear. It is not regulated and neither expressly forbidden under law. It all depends on a particular IVF clinic; it may be direct payment or compensation for the harm caused to health, physical sufferings and etc, and the price varies significantly dependently on the region, a particular clinic, and patients' particular requests regarding the gametes.

Serbia

Article 28 (paragraph 1-3) regulates Prohibition of Gain from BMAF Procedures

Prohibitions referred to in paragraph 1 to 3 above shall not be applicable to:

- 1) living donor compensation for loss of earnings or other income for time spent in a medical institution or during recovery, or during temporary inability to work, or compensation for other eligible expenses that the donor has had due to the procedure of retrieval of reproductive cells (transport, accommodation, food costs etc.);
- 2) eligible compensation in connection with payment for medical or other services related to retrieval of reproductive cells;
- 3) compensation in the event of excessive damage arising from the retrieval of reproductive cells.

<u>Slovenia</u>

Financial rewards are explicitly prohibited. However, any expenses generated by the donation may be reimbursed (Art. 10).

<u>Spain</u>

The National Commission for Assisted Reproduction approved in 1998 the figure of 600 euros as compensation for the expense and inconvenience of the donor. Currently some private clinics are paying 1000 euros.

United Kingdom

The HFEA permits UK licensed clinics to compensate egg donors up to the fixed amount of £750 per cycle of donation and up to £35 per clinic visit for sperm donors. Guidance is provided to clinics in the HFEA's Code of practice (https://www.hfea.gov.uk/media/2793/2019-01-03-code-of-practice-9th-edition-v2.pdf) and HFEA General Directions (https://ifqtesting.blob.core.windows.net/umbraco-website/1547/2017-04-03-general-direction-0001-version-4-final.pdf).

The HFEA also permits benefits in kind, such as egg sharing. Egg sharing arrangements where a woman who needs IVF treatment agrees to share her eggs with another woman

needing donated eggs, in return for free or reduced rate treatment. Again guidance is contained in the HFEA code of practice: https://www.hfea.gov.uk/media/2793/2019-01-03-code-of-practice-9th-edition-v2.pdf

<u>Canada</u>

As mentioned above, pursuant to section 7, the purchase of sperm or eggs is prohibited. Moreover, the purchase and sale of an *in vitro* embryo is prohibited. It is noteworthy that in section 7, "purchase" or "sell" includes to acquire or dispose of in exchange for property or services. In other words, it is prohibited to donate gametes in exchange for free fertility services. However, the reimbursement of a sperm or egg donor's receipted expenditures relating to the act of donation will be permitted upon the coming into force of section 12 and the corresponding regulations. In addition, the reimbursement of any person for receipted expenditures incurred in the maintenance or transport of an in vitro embryo will also be permitted.

8. Are there specific criteria for donation of the following?

- a. Sperm
- b. Oocytes
- c. Embryos

| Country | а | b | С | Country | а | b | С |
|-------------------------|------|------|------|------------------------|------|------|------|
| Albania | | | | Luxembourg | Yes* | Yes* | Yes* |
| Andorra | * | | | | | | |
| Armenia | | | | Malta | No* | No* | No* |
| Austria | Yes* | Yes* | - | Republic of Moldova | | | |
| Azerbaijan | Yes | - | - | Netherlands* | Yes* | Yes* | Yes* |
| Belgium | Yes* | Yes* | Yes* | Norway | Yes* | No | No |
| Bosnia & Herzegovina | N/A | N/A | N/A | Poland | Yes* | Yes* | Yes* |
| Bulgaria | | | | Portugal | No | No | No |
| Croatia | Yes* | Yes* | Yes* | Romania | | | |
| Cyprus | No | -* | -* | Russian Federation | Yes* | Yes* | No* |
| Czech Republic | Yes* | Yes* | Yes* | San Marino | - | | |
| Denmark** | Yes* | Yes* | Yes* | Serbia | Yes | Yes | Yes |
| Estonia | Yes | Yes | Yes | Slovakia | Yes* | Yes* | Yes* |
| Finland | Yes* | Yes* | Yes* | Slovenia | Yes* | Yes* | - |
| France | Yes* | Yes* | Yes* | Spain | Yes* | Yes* | Yes* |
| Georgia | * | * | * | Sweden | Yes* | Yes* | - |
| Germany | Yes* | - | - | Switzerland | Yes* | - | - |
| Greece | Yes* | Yes* | Yes* | "FYROM" | - | - | - |
| Hungary | Yes* | Yes* | Yes* | Turkey | No | No | Yes* |
| Iceland | Yes* | Yes* | * | Ukraine | No* | No* | No* |
| Ireland | Yes* | Yes* | Yes* | United Kingdom | Yes* | Yes* | Yes* |
| Italy | Yes | Yes | No | Canada | Yes* | Yes* | Yes* |
| Latvia | Yes* | Yes* | Yes* | Israel | Yes* | Yes* | No |
| Lithuania** | Yes* | Yes* | Yes* | | | | |

<u>Andorra</u>

The donors of female and masculine gametes must be over 18 years and no older than 37 for the female donors and 45 for the male ones. In addition, they must be in good health. The maximum authorised number of children born to Andorran nationals or residents of Andorra of the same gamete donated, is limited to 1, unless this concerns the reproductive process of the same recipient.

<u>Austria</u>

Written consent of the donor is required. Donation can only be done to a specifically authorized hospital. Age limit for egg donation: 30 years (donor), 45 years (recipient)

<u>Belgium</u>

The 2007 Act states that gamete retrieval is available to adult women up to the age of 45 years. Retrieval of gametes, supernumerary embryos, gonads or gonad fragments for cryogenic storage may be carried out, on medical advice, on a minor, however.

Donations of supernumerary embryos or gametes for eugenic purposes or for the purposes of sex selection are prohibited.

There must be a written agreement between the donor and the accredited fertility centre. The law does not specify any medical criteria for harvesting.

Croatia

Donors are assessed according to the requirements of the EU Tissues and Cells Directives and other professional standards comprising at least: assessment of the risk for transmission of blood-borne diseases (history of behaviour and testing), medical history, physical examination, genetic testing.

Cyprus

It is not possible to say whether there are specific criteria for the above mentioned donations as they are not legally regulated issues.

Czech Republic

Age limit, health status, informed consent.

Denmark

In general, all men can donate sperm and all women under the age of 35 years can donate oocytes if this does not involve any known serious genetic or infectious risk. The tissue establishment in charge of testing, processing, preservation, storage or distribution of human tissues and cells has the responsibility to ensure the quality of sperm and oocytes. Donation of embryos is only possible for research purposes, not for assisted reproduction.

Finland

a) and b) Act on Assisted Fertility Treatments (*laki hedelmöityshoidoista*; 1237/2006) requires the donor to be 18 years old. In medical practice, maximum age limits have been set up by clinics and may vary between them. Donation of gametes should not pose a health hazard to the donor and donors should have no serious hereditary diseases or any communicable diseases, which may cause a serious illness to the woman receiving assisted fertility treatment or to the child. This is ensured by means of a health examination of the donor. Informed consent is required. A donor may specifically consent to the use of sperm for MAP of single women.

c) Only surplus embryos resulting from MAP may be donated with informed consent from both donors.

France

In principle, the donor should already be a father or mother, although this may not always be the case. The donor may then be asked whether he or she wishes to have part of his/her gametes collected and stored for medically assisted procreation at their behest at a later date. Donor recruitment takes account of age, general state of health, personal and family history, results of health tests, and findings from sperm characteristics or gynaecological examination (in particular assessment of ovarian function).

A psychological interview is held.

A full and documented study of the genealogical tree of the gamete donor is made in order to identify risk factors for transmission of a genetic anomaly to the child. Any suspected anomaly is an indication to complete the work-up. A karyotype is recommended.

In practice, age limits are 18 to 45 for male and 18 to 37 for female donors.

Hungary

For a. and b. In a concrete intervention with gamete donation only one and the same person can be the donor.

The donation is prohibited (Act §171 (7))

- a) if the donor has a pathology excluding donation (Decree, appendix Nr. 3)
- b) the donor refuses giving his/her personal data required (Act §171 (3))
- c) if the donor does not appear in person at the center

Age limit is 35 years (Act §171 (1))

Embryo donation is anonymous

Further conditions for embryo donation are detailed in Act §176

Georgia

LHC: No DL-RHRR: Yes

DL-RHRR:

A gamete donor must be a legally competent man or woman above 18 years of age, who has none of the diseases defined by law.

The fusion of the sperm or ovum of genetic relatives for medically assisted reproductive technologies is prohibited.

The gamete can be retrieved from a deceased male person, only if he has given an advanced directive for taking his gametes after his death for homological artificial insemination, or for *in vitro* fertilization of the ovum of his spouse, married under the rules defined by the legislation of Georgia. On the other hand, taking ovum or an ovary from a deceased woman for the implementation of medically assisted reproductive technologies is prohibited.

Germany

Gametes may be used for medically assisted procreation only after full medical assessment and if their use is medically indicated and the protection of the recipient's and the child's health is guaranteed (section 6 subs. 1 of the Tissues and Cells Regulation of the Transplantation Act). The use of sperm cells for heterologous fertilisation as a medically assisted procreation technique furthermore requires that the sperm donor is medically assessed as suitable for sperm donation with regard to his age, state of health and medical history and that the use of the donated sperm will not pose any health risks to others. The necessary donor information must be collected by questionnaire and by means of a subsequent personal interview with the donor by the physician.

An age limit exists for eligibility to cost coverage by the health insurance funds (see response to question 4).

Greece

Donors must have reached the age of majority with full judicial capacity. Regarding sperm donors must be under 40 years of age whereas for oocytes donors must be under 35 years of age. These age limits can be extended to 50 and 40 years of age respectively in case of donation of fertilized ova or when there is a serious reason, after authorization by the National Authority on MAR. In these cases, special information to the recipients is required regarding increased risk for genetic diseases as well as the need for prenatal testing.

Donors are submitted to special medical and laboratory tests defined (due to scientific developments) by the National Authority.

Iceland

See regulation: http://eng.heilbrigdisraduneyti.is/laws-and-regulations/nr/686

(Artificial insemination with donor sperm shall only be carried out if the fertility of the man is impaired, he has a serious hereditary disease or there are other medical reasons to use of donor sperm. (Article 8)

In vitro fertilization shall only be carried out with the gamete of the couple. It is however permitted to use donor gamete if the fertility of the man or the woman is impaired, either of them has a serious hereditary disease or there are other medical reasons to use of donor gamete. It is prohibited to carry out in vitro fertilization unless the gamete of either partner or either cohabitant is used. Donation of embryos and surrogacy is prohibited. (Article 9))

Ireland

The Children and Family Relationships Act 2015, sets out a number of criteria in relation to the consent of gamete/embryo donors. For instance, a donor must be over 18 and must give consent in writing, having confirmed that s/he has been informed that s/he will not be the parent of a child born through the donation. The consent must be witnessed. The donor must agree, when consenting, to the inclusion of information about him/her on the National Donor-Conceived Person Register. The consent must also indicate that the donor understands that a donor-conceived child may seek to contact her/him. Assisted human reproduction clinics should be satisfied that where donated gametes/embryos are being imported from another jurisdiction, the consent process in the other jurisdiction is in line with the stipulations set out above. Under the proposed assisted human reproduction legislation, donors will undergo medical screening in accordance with requirements set out under SI No. 158/2006 European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006

Latvia

For sperm age limit 18-45.

For oocytes 18-35.

If checking on sexually transmitted disease STD, Hepatitis B, C are positive.

If General health are not in good condition.

If in anamnesis have genetic diseases.

Lithuania**

Following the Law on MAP it is forbidden to procure and/or use dead person's gametes for the MAP. If a person, whose gametes are being stored in a gamete bank, dies, his/her gametes must be destroyed. The dead person's gametes can be used for the MAP of a concrete person, only if the dead person had given his/her consent to use his/her gametes while still alive.

A specialist providing MAP services must check the legitimacy of the procedure, its safety in respect to the donor, recipient and the child (children) who could be born after MAP, and make appropriate records in the medical documents, before the procedure.

The procedure of collection, preparation, storage, distribution and usage of gametes <u>and embryo donation</u> are established by the Minister of Health of the Republic of Lithuania.

Luxembourg

In fact there is neither a collection nor a bank in Luxembourg. The service functions in collaboration with a foreign bank.

Malta

There are no legal provisions.

Netherlands

Within the Embryos Act, there are criteria to guarantee the free consent of the donor. In addition to that, the professional Guideline states that oocyte donation is contraindicated for

- women who are older than 40 years,
- women who have a higher risk on complications is case of oocyte-stimulation- or punction;
- women with sexually transmitted diseases who cannot be cured
- women with a genetic disease within their family.

These contraindications are absolute. In addition, some women have a relative contraindication to oocyte donation, for instance women who have no children themselves and are under the age of 30.

Norway

Criteria for donation of sperm:

- good health (both physical and mental) and "normal" sperm (count and motility)
- no known contagious diseases
- no known serious inheritable diseases (based on the donors information. No chromosomal analysis or tests for single gene disorders will performed)
- ideally between 25 and 45 years of age
- should have children of his own.

The last two criteria are instructive.

To prevent the use of sperm from diseased donors and to ensure that information about the donor (name, address) can be provided to the child when reaching majority, Norwegian citizenship or permanent habitual permission is required.

There will be an interview to ensure an altruistic motivation. Homosexual men may be accepted. Donation of oocytes and embryos is forbidden.

Testing of donors follow the procedures and criteria set out in the EU Directives on tissues and cells.

Poland

Criteria for donation of sperm:

There are no legal provisions on the subject.

Some questions are covered by the Opinion of the Polish Association of Obstetricians. Clinics' internal regulations define the medical criteria applicable to donors. These include: age: 30 - 45 years (correlation between the risk of a genetic disorder, such as Down's syndrome, and age), state of health (absence of mental, systemic, tumour or infectious disease), and testing for viruses and sexually transmitted diseases. Where there is a high risk of the mother transmitting a genetic disorder to her offspring, the sperm donor must undergo

exclusion tests for the same autosomal recessive gene. The donor's blood group must also be known, to make sure it is compatible with the parents' blood groups.

Sperm tests are carried out in conformity with WHO standards. Sperm is only preserved if bacteriological tests yield negative results. Donated sperm must be frozen for 6 months prior to the first insemination.

Russian Federation

Apart from medical/genetic criteria, the sperm and oocyte donors shall meet the following requirements. Both the sperm and oocyte donors shall be of the age between 18 and 35, and be physically and mentally healthy. Sperm and oocyte donors can be anonymous and non-anonymous.

Technically, in the law there are no criteria for being a parent and no age restrictions either.

<u>Slovakia</u>

For sperm donation - health, state.

For oocytes donation and for embryos donation - parents, age.

Slovenia

A person may donate his/her gametes to one center only (Art. 11).

The donors must be of legally mature age, healthy and mentally competent (Art. 14).

Donated gametes may not be used in cases where that would constitute illicit consanguinity (Art. 14).

Spain

- Donor: Adult (18 years old or more) and legally capable.
 - Sperm donor: no more than 50 years old. Oocyte donor: no more than 35 years old.
- No lucrative or commercial purposes.
- Good psychophysical health and they do not suffer from genetic, hereditary or transmissible infectious diseases to offspring.
- Written contract.

Sweden

The donor is assessed on numerous conditions. The donor has to be in good health, physically and mentally. He/she must understand the consequences; He/she has no authority over the conceived child, he/she should not have regrets and it is preferred that he/she has a social network to cope with any possible thoughts, and the donor has to accept the possibility that children may in the future ask for his identity and make contact, as donation by Swedish law is unanonymous. The donor must be above 18 and his/her maturity is assessed in line with the above conditions. The donor must give written consent and has the option to withdraw the consent before the oocyte is fertilized.

The donor must be alive at the time of fertilization.

Switzerland

Medical criteria (good health).

Turkev

Embryo should be on the 5th day after fertilisation, it can be surplus embryo at the IVF clinic for which informed consent of the couples was obtained. It should be donated for medical reasons, not for research purposes.

<u>Ukraine</u>

All donors investigated for TORCH (toxoplasmosis, syphilis, rubeole, cytomegalovirus (CMV), herpes simplex virus (HSV)) infection, genetical and medical tests.

United Kingdom

a) The HFEA provides guidance to UK licensed clinics in its Code of Practice: https://www.hfea.gov.uk/media/2793/2019-01-03-code-of-practice-9th-edition-v2.pdf

Clinics should refer to the relevant professional body guidelines on age limits before accepting gametes for the treatment of others. Gametes for the treatment of others should not be taken from anyone under the age of 18. A donor must not be selected because they are

known to have a particular gene, chromosome or mitochondrial abnormality that, if inherited by any child born as a result of the donation, may result in that child having or developing:

- a) serious physical or mental disability
- b) A serious illness
- c) Any other serious medical condition

The use of gametes from donor known to have an abnormality as described above, should be subject to consideration of the welfare of any resulting child and should normally have approval from a clinical ethics committee.

Canada

Specific criteria for donated reproductive material do exist. Section 9 of the Act prohibits a person from obtaining sperm or eggs or using sperm or eggs so obtained from a donor who is under 18 years of age. Certain exceptions do exist, namely, sperm or eggs may be obtained from a person under 18 years of age for the purpose of preserving the gametes or for the purposes of creating a human being that is reasonably believed to be raised by the donor. Further, once the relevant provision of the Act comes into force, a licensee will not be able to accept a donation of reproductive material or an in vitro embryo unless the licensee has obtained from that person the health reporting information (defined in the Act) required to be collected under the regulations. Therefore, specific information must be provided before donations are accepted.

With respect to semen, in 1996, the Processing and Distribution of Semen for Assisted Conception Regulations were promulgated under the Food and Drugs Act. These regulations set out stringent health and safety requirements specifically concerning the processing and distribution of third-party donor sperm that is used or intended for use in an assisted human reproduction procedure. These requirements stipulate the necessary serological and microbiological tests that must be performed before third party donor sperm can be used in an assisted human reproduction (AHR) procedure. The Processing and Distribution of Semen for Assisted Conception Regulations appears in the Addendum.

Israel

Criteria of health and appropriate psychological profile (to ensure donations are altruistically motivated).

9. Are there specific non-medical criteria for selection of gametes/embryo to be used for MAP (e.g. matching appearance of donor and future parent(s))?

| Country | Reply | Country | Reply |
|-------------------------|-------|-----------------------|-------|
| Albania | | Luxembourg | Yes* |
| Andorra | Yes* | | |
| Armenia | | Malta | No* |
| Austria | No | Republic of Moldova | |
| Azerbaijan | No | Netherlands | No |
| Belgium | Yes* | Norway | Yes* |
| Bosnia & Herzegovina | N/A | Poland | No* |
| Bulgaria | | Portugal | Yes* |
| Croatia | - | Romania | |
| Cyprus | No | Russian Federation | Yes* |
| Czech Republic | No* | San Marino | - |
| Denmark** | Yes | Serbia | - |
| Estonia | Yes | Slovakia | Yes |
| Finland | Yes* | Slovenia | No* |
| France | Yes* | Spain | Yes* |
| Georgia | * | Sweden | Yes* |
| Germany | No | Switzerland | Yes* |
| Greece | Yes* | "FYROM" | - |
| Hungary | Yes* | Turkey | No |
| Iceland | Yes* | Ukraine | Yes* |
| Ireland | No | United Kingdom | Yes* |
| Italy | No | Canada | * |
| Latvia | Yes | Israel | No |
| Lithuania | No | | |

Andorra

Major phenotypic and immunological similarity, [made] possible by the medical team.

Belgium

In practice, the centres try to avoid too great a dissimilarity between donors and recipients. The law of 2007 specifies that pairing between donor and recipient may not be considered as a practice with eugenic character.

Czech Republic

But usually the blood group and appearance are matched, if possible.

Finland

When using donated gametes, Section 5 of Act on Assisted Fertility Treatments (*laki hedelmöityshoidoista*; 1237/2006) requires the attending physician to select gametes whose donor resembles in appearance the parent of the child to be born, unless otherwise requested by the person receiving treatment.

France

Matching between the recipient couple and the male or female donor whose gametes are used is recommended as desirable under the rules of good practice. It takes into account the physical characteristics and blood groups of the recipient couple.

Georgia

LHC: <u>No</u> DL-RHRR: Yes

According to the draft Law on Reproductive Health and Reproductive Rights a couple or a single woman have the right to choose a donor on the basis of the donor's age, appearance, ethnic background, and health condition. However, information on the identity of a sperm donor is confidential.

Greece

According to the Law the selection of the donor is the responsibility of the MAR Unit. During this selection other criteria like blood group (Rhesus) as well as phenotypic characteristics are taken into consideration. The same criteria apply to fertilized ova donation.

Hungary

For gametes, the appearance, as well as eventual illness of the donor are registered data. For oocyte donation, the level of eventual parent status must be considered (Act § 171 (4)). For embryo donation, embryos issuing from the same couple may only be implanted in MAP for maximum two different persons. (Act § 175 (4)).

Iceland

If donated gametes are used, the doctor in charge of the treatment shall select the appropriate donor. A donor of gamete shall be healthy and have no hereditary diseases. Necessary tests shall be carried out to ensure that the donor is healthy and fertile and to prevent the transmission of diseases with the gamete. If imported gametes are used, the fulfilment of the aforementioned demands must be ensured. A doctor shall endeavour to realize the wishes of applicants that the build, height, colour of eyes and hair and the blood type of the gamete donor is as closely resembling the parent's as is possible . (art.17 reg.568/1997)

Luxembourg

Five classic characteristics (blood group, complexion, eyes, colour of hair, height).

Malta

There are no legal provisions.

<u>Norway</u>

A national registry of donors has been established to ensure the right for children that are conceived by donor sperm to know the identity of the donor when reaching the age of majority (in Norway, 18 years). Sperm from one donor can be used until 8 children are born, in up to 6 different families. This is not legally established but follows from a circular from the Directorate of Health.

Poland

There are no legal provisions on the subject.

In practice basic physical and ethnic resemblance (skin colour) is taken into account.

Portugal

Matching appearance of donor and future parent(s)

Russian Federation

These are not quite criteria, but the patients/recipients have the right to choose donors on the basis of information about donors' phenotype, nationality, ethnic origin, appearance, colour of the eyes, hair etc.

Slovenia

Such non-medical criteria are not contained in the law, but may be considered in practice, as far as circumstances allow.

Spain

Matching appearance and immunological compatibility of donor and future parent(s).

Sweden

The responsible physician shall choose a matching appearance.

Switzerland

Matching appearance of donor to recipient male parent

<u>Ukraine</u>

We take into account phonotypical characteristics of donors and recipient.

United Kingdom

Centres are not expected to match the ethnic background of the recipient to that of the donor. Where a prospective recipient is happy to accept a donor from a different ethnic background, the centre can offer treatment, subject to the normal welfare of the child assessment.

Canada

The Act does not address selection criteria for gametes / embryos to be used for MAP. However, it is a relatively common practice for fertility clinics to try to match the ethnic origin or physical characteristics of a sperm donor with the future father. This is less common with respect to egg donors and future mothers because the selection of eggs available for donation is not as plentiful.

10. Are there special measures for the prevention of consanguinity? (E.g. official register, limited number of donations.)

| Country | Reply | Country | Reply |
|-------------------------|-------|-----------------------|-------|
| Albania | | Luxembourg | No* |
| Andorra | Yes* | | |
| Armenia | | Malta | * |
| Austria | Yes* | Republic of Moldova | |
| Azerbaijan | No* | Netherlands* | Yes* |
| Belgium | Yes* | Norway | Yes* |
| Bosnia & Herzegovina | N/A | Poland | No* |
| Bulgaria | | Portugal | Yes* |
| Croatia | Yes | Romania | |
| Cyprus | * | Russian Federation | No |
| Czech Republic | Yes* | San Marino | - |
| Denmark | Yes* | Serbia | Yes |
| Estonia | Yes | Slovakia | Yes* |
| Finland | Yes* | Slovenia | Yes* |
| France | Yes* | Spain | Yes* |
| Georgia | * | Sweden | Yes |
| Germany | Yes* | Switzerland | Yes* |
| Greece | Yes* | "FYROM" | * |
| Hungary | Yes* | Turkey | No |
| Iceland | Yes* | Ukraine | Yes* |
| Ireland* | * | United Kingdom | Yes* |
| Italy | Yes | Canada | Yes* |
| Latvia | Yes* | Israel | No* |
| Lithuania** | Yes* | | |

<u>Andorra</u>

A register for assisted human reproduction.

Austria

Sperm and eggs of a donor may only be used in favour of three couples. The donation by a certain donor is permitted only to one single hospital.

<u>Azerbaijan</u>

Consanguinity (between cousins) is very widespread in Azerbaijan and these marriages are not forbidden.

Belgium

The 2007 Act states that supernumerary embryos from the same donor or couple of donors or gametes from the same donor, must not result in births in more than 6 different women.

Croatia

Official Registry is about to be established. Number of donations is limited up to 3 children born (after 3 births donations from donor that is biological parent shall be discarded).

Cyprus

It is unknown whether there are special measures for the prevention of consanguinity.

Czech Republic

Limited number of donations, but this is a recommendation, not a law.

Denmark

A sperm donor may not have more than twelve offsprings.

In cases where the donor (sperm or oocytes) have more than twelve offsprings, donations can still be made from the donor to help MAP for multiple siblings by the same donor, if a single woman or one of the couple has a child with the donor in advance.

Frozen embryos, fertilized from one donor (oocytes), where the number of viable pregnancies established with oocytes from the same donor subsequently has exceeded 12, may continue to be used.

Frozen eggs, fertilized with sperm from one donor, where the number of viable pregnancies established with sperm from the same donor subsequently has exceeded 12, may continue to be used.

Finland

When the gametes of a donor have provided progeny to five MAP recipients, gametes donated by the said donor may no longer be used in MAP provided to others.

France

A maximum of ten children may be born from the use of gametes originating from the same donor.

This is ensured by a procedure set up in ova and sperm storage centres in France (CECOS). If the donor belongs to a population group at known risk of a recessive disorder, heterozygosity must be screened for whenever possible.

When data from the medical history and physical examination reveal a factor of relative risk, the protocol ensures that donor gametes are never assigned to a couple in whom the recipient person presents the same risk factor. The advice of a geneticist may be sought.

Hungary

The number of descendants from the same gamete donor with different persons included in MAP intervention cannot exceed 4.

MAP intervention can only be requested by persons who are not in level of parentage that would prevent legal marriage between them (Civil Code § 4:12 (1) a) and b), i.e. between linear relatives and brothers/sisters).

In MAP with persons in other level of consanguinity the physician indicating MAP has to previously consult with the Regional Genetic Center (Decree §1 (3)). Embryos issuing from the same couple may only be implanted in MAP for two different persons (Act § 175 (4)).

Georgia

LHC: <u>No</u> DL-RHRR: <u>Yes</u>

The following two principles are introduced in the draft law (DL-RHRR) to avoid consanguinity:

- a) Gametes from one person can be used no more than three times (that result in childbirth);
- United register of gamete donors is to be established, which will collate data of the persons participating in medically assisted reproductive technologies using donated gametes.

Germany

Limited number of donations in practice.

The Model Guidelines of the German Medical Association state_in paragraph 5.3.1: "The physician shall take care to ensure that an individual donor does not produce more than ten pregnancies."

Greece

The number of children born from gametes by the same donor must not exceed 10, unless it is about the birth of a new child of a couple which has already had a child from the gametes of this particular donor. The National Authority may determine the exact number of children resulting from the use of gametes by the same donor, depending on the population of a certain region and other special conditions.

[Comment: the law refers to the actual number of children *born* and not to the number of cycles of treatment attempted].

Iceland

Indirectly, see art.18 reg.568/1997 (If a donor wishes to remain anonymous, health workers are obliged to ensure that this is respected. In this case, the donor may neither receive information about the couple receiving the donated gamete or the child, nor the couple or the child receive information about the donor. If a donor does not wish to remain anonymous, the institution shall preserve information about him in a special file. If the donation of gamete leads to the birth of a child, information about the child and the couple who received the gamete shall be kept in the same file. A child born on account of a gamete donation where the donor does not wish to remain anonymous can at the age of 18 gain access to a file pursuant to paragraph 2 for the purpose of obtaining information about the identity of the donor. If a child receives information about the gamete donor at the institution, the said institution shall as soon as possible inform the donor that the information has been given.)

Ireland

Ireland has a relatively small population size, which could increase the risks of inadvertent consanguinity between individuals conceived using gametes from the same donor. It is proposed that the assisted human reproduction legislation will place a maximum limit of four families to which gametes/embryos from the same donor can be donated.

Latvia

No more than three children can be born from one donor, furthermore, special means are taken if the children born from donor have genetically hereditary disease.

Lithuania**

All information concerning gametes held in the gametes' bank, including information about the stored and used human embryos, and children born after MAP must be registered in the MAP Information System.

Luxembourg

The straws of sperm come from abroad.

Malta

There is no legal framework.

Netherlands

There is a professional guideline that limits the number of offspring of one donor to 25 children or 12 families. Because clinics now don't have a legal basis to check if a donor also donates in other clinics, there is a legal change in preparation which allows national registration of donors, so that the limited number of offspring can be monitored.

Norway

There will be a national registry of donors to ensure the right for children that are conceived by donor sperm to know the identity of the donor when reaching the age of majority (in Norway, 18 years), and to ensure that a donor is only registered with one of the two sperm banks. Sperm from one donor can be used until 8 children are born.

Poland

There is no legal provisions on the subject.

Clinics' internal regulations may settle this question. According to the Opinion of the Polish Association of Obstetricians, the number of pregnancies obtained using sperm from the same donor may not exceed five.

Portugal

Limited number of donations

Slovakia

Limited number of donations

Slovenia

Donated gametes may be used until children are born in two different families (Art. 29).

<u>Spain</u>

No donor can be parent of more than six children. This is controlled through the National Registry of Donors and the banks of the clinics of assisted reproduction.

Sweden

It is not recommended that a donor conceives more than 12 children (2 children in 6 families). There is no national register.

Switzerland

8 children only.

"FYROM"

With the exception of the occasional donor for inseminations with fresh sperm which may be done outside of any control, other donor procedures have not been performed in the country.

Ukraine

Very strict measures.

United Kingdom

The HFEA maintains a register of all donors and patients who have had a child using donor gametes. Children born following donor conception who intend to enter into an intimate physical relationship can submit a joint application to the HFEA to establish whether they are genetically related. Also, anyone who intends to marry, or enter into a civil partnership may submit a joint application to establish whether they are genetically related. A single donor can contribute to a maximum of 10 families. After this limit is reached the donor can no longer be used, one reason for this being to reduce the risk of consanguinity.

Canada

Pursuant to the Act, a regulatory body will be created to oversee the area of assisted human reproduction and related research in order to protect and promote the health and safety of Canadians using Assisted Human Reproduction (AHR) technologies. This Agency will be known as the Assisted Human Reproduction Agency of Canada.

Once established, the objectives of the Agency will be:

- to protect and promote the health and safety, and the human dignity and human rights, of Canadians in relation to AHR; and
- to foster the application of ethical principles in relation to AHR.

The Agency will perform several essential functions under the legislation, including:

- issuing, renewing, amending, suspending or revoking licences for AHR procedures or research using in vitro embryos;
- inspecting AHR clinics and research laboratories to ensure health and safety;
- collecting and analysing health reporting information;
- providing advice to the Minister of Health on AHR issues; and
- monitoring and evaluating national and international developments related to AHR.

As part of its function to collect and analyse health reporting information, the Agency will store identifying information for health and safety reasons, such as being able to verify consanguinity for individuals born using donor genetic material. This would ensure that individuals who wish to marry and reproduce are not genetically related. In addition, the Act provides that regulations may be made with respect to the number of children that may be created from the gametes of one donor through the application of assisted reproduction procedures.

Israel

To preserve anonymity there is no register (although the sperm bank keeps records for medical purposes only).

11. In a homosexual couple, is a legal relationship possible between a child and the partner of his or her legal parent?

| Country | Reply | Country | Reply |
|-------------------------|-------|------------------------|-------|
| Albania | | Luxembourg | No* |
| Andorra | Yes* | | |
| Armenia | | Malta | No |
| Austria | Yes* | Republic of Moldova | |
| Azerbaijan | No | Netherlands* | Yes* |
| Belgium | Yes* | Norway | Yes* |
| Bosnia & Herzegovina | N/A* | Poland | No* |
| Bulgaria | | Portugal | Yes* |
| Croatia | N/A | Romania | |
| Cyprus | * | Russian Federation | No* |
| Czech Republic | No* | San Marino | |
| Denmark | Yes* | Serbia | No |
| Estonia | No | Slovakia | No |
| Finland | Yes* | Slovenia | * |
| France | Yes* | Spain | No |
| Georgia | No | Sweden | Yes* |
| Germany | Yes* | Switzerland | Yes* |
| Greece | No* | "FYROM" | No* |
| Hungary | No* | Turkey | No |
| Iceland | Yes* | Ukraine | No |
| Ireland* | Yes* | United Kingdom | Yes* |
| Italy | No* | Canada | Yes* |
| Latvia | No | Israel | Yes* |
| Lithuania | No | | |

<u>Andorra</u>

Surrogate mothers.

Austria

The legal mother's partner is automatically the other parent of the child if that partner has given written consent for the PMA with a sperm donation.

Belgium

The Act of 18 May 2006 amended certain provisions of the Civil Code to allow same-sex adoption.

Bosnia & Herzegovina

MAP legal only for heterosexual couples

Croatia

Homosexual couples are not permitted to access MAP

Cyprus

It is not possible to say whether in a homosexual couple, a legal relationship is possible between a child and the partner of his or her legal parent. There are no referred cases of homosexuals having a child.

Czech Republic

But this was breached last week (half of May 2018). A gay couple who brought a child from surrogacy in the USA, was recognized by the Supreme Court as a full-fledged fathers. The reason was the best interest of the child.

Denmark

By December 2013 the Children Act was amended with rules on co-maternity. Co-maternity can be established when the mother has been treated with assisted reproduction and has a female spouse or partner who has agreed to the treatment.

In other cases, homosexual couples have the same rights to adoption as heterosexual couples, which also include the possibility for stepchild adoption.

Finland

If partners living in a same-sex relationship are married or have registered their partnership, a partner may adopt the other partner's child. According to the new Maternity Act which entered into force on 1 April 2019, the maternity of a partner in a female same sex couple can be recognised on the basis of valid consent to fertility treatments.

France

The partner of the legal parent may adopt (simple or full adoption) the child of his or her partner.

Hungary

MAP is restricted to heterosexual couples.

Germany

German law includes the following provisions governing the legal relationship between the child and the partner of the legal parent:

- Authority of the (registered) partner of a parent who has the sole custody of the child to have a say in matters of daily life (so-called "lesser custody" section 9 of the Act on Registered Life Partnerships),
- Right of contact, if a "family-like social relationship" has evolved between the parent's partner and the child (section 1685 subs. 2 Civil Code),
- Option of the (registered) parent's partner to seek a court residence order on behalf of the child if his/her partner dies or is prevented from exercising the parental custody for other reasons and the non-residential parent claims the child (section 1682 sent. 2 Civil Code)

Pursuant to section 9 subs. 7 of the Act on Registered Life Partnerships, a (registered) partner is entitled to adopt his/her partner's biological child, but not the adopted child his/her partner adopted alone. The German Constitutional Court is currently examining whether it is constitutional that the so-called "step-child adoption" is limited to the partner's biological child.

Greece

This law does not include any provisions for homosexual couples.

Iceland

Art. 6, Act no. 87/1996 (The provisions of the Adoption Act relating to spouses shall not apply to registered partnership. A person in registered partnership can however adopt a child of the other partner of whom that partner has custody, provided the child has not been adopted from another country. Nor shall statute provisions on artificial insemination apply to registered partnership.

Statute provisions involving particular rules depending on the sex of a married spouse shall not apply to registered partnership. 1). Provisions of international agreements to which Iceland is a party shall not apply to registered partnership unless approved by the other party.)

Ireland

Under the Children and Family Relationships Act 2015, the parents of a donor-conceived child who is born as a result of a donor assisted human reproduction procedure are

- (a) the mother, and
- (b) the husband, civil partner or cohabitant, as the case may be, of the mother.

The Act of 2015 does not encompass surrogacy.

Italy

The law limits access to MAP to heterosexual couples, married or living under the same roof (Art 5).

Luxembourg

Currently no legislation.

Netherlands

When two women are married, the second mother can easily become the legal mother. In other cases, an adoption procedure is required.

Norway

Rules of parentage for the second mother (the women not giving birth) have been established.

Poland

There are no legal provisions on the subject.

A legal relationship between a child and the homosexual partner of his or her legal parent would be considered contrary to the spirit of Polish law on families and descent, which defines the family as the union of two individuals of the opposite sex.

Portugal*

Homosexual marriage, adoption and co adoption are legal in Portugal

Russian Federation

Russian law currently does not provide for any possibility to establish the legal relations between a child and a same-sex partner of the child's parent (neither through registration as a parent, nor through adoption).

It is unlikely that it may be possible in foreseeable future

Slovenia

No legal provisions.

Sweden

Adoption is possible.

Switzerland

This has nothing to do with MAP.

"FYROM"

No legal regulations.

United Kingdom

The legal provisions on who can be a child's legal parent and what conditions must be met is set out in the HFEA Act.

Where a woman in a civil partnership is seeking treatment using donor sperm, or embryos created using donor sperm, the woman's civil partner will be treated as the legal parent of any resulting child unless, at the time of placing the embryo or sperm and eggs in the woman, or of her insemination:

- a) A separation order was in force, or
- b) It is shown that the civil partner did not consent to the placing in her of the sperm and eggs, or embryos, or to the insemination

Where a woman is being treatment together with a female partner (not a civil partner) using donor sperm, or embryos created with donor sperm, the female partner will be the other legal parent of any resulting child if, at the time the eggs and sperm, or embryos, are placed in the woman or she is inseminated, all the following conditions apply:

- a) Both the woman and her female partner have given a written, signed notice (subject to the exemption for illness, injury or physical disability) to the centre consenting to the female partner being treated as the parent of any resulting child
- b) Neither consent was withdrawn (or superseded with a subsequent written note) before insemination/transfer, and
- c) The patient and the female partner are not close relatives (within prohibited degrees of relationship to each other as defined in section 58(2), part 2, HFE Act 2008)

Canada

In Canada, adoption laws are within the jurisdiction of the provinces and territories. In large part, whether or not a legal relationship is possible between a child and the same-sex partner of his or her legal parent depends on the provisions in the relevant legislation setting out who can apply to adopt. The provisions detailing who can apply to adopt have been successfully challenged by same-sex partners on the basis that they violated equality rights in Nova Scotia, Alberta and Ontario. Consequently, these jurisdictions have amended their legislation to allow for same-sex partners to adopt their partner's child. Other jurisdictions in Canada have also changed their adoption legislation to allow for same-sex partners to adopt the child of their partner.

<u>Israel</u>

The legal position was decided in a specific case which came before the Supreme Court.

Surrogate mothers (see Appendix I)

- 12. Is surrogacy permitted in your country?
 If yes, describe all conditions regulated by law
- 13. If yes, can the surrogate mother be legally remunerated?
- 14. If surrogacy is forbidden in principle, are there exceptions?
- 15. Are you aware of illegal practices in your country?

<u>Section II - Right to know about his or her biological origin for children born</u> after MAP

- 16. Are donation of the following anonymous?
 - a. Sperm
 - b. Oocytes
 - c. Embryos

| Country | а | b | С | Country | а | b | С |
|-------------------------|-------------------|-------------------|------|------------------------|-------------|-------------|-------------|
| Albania | | | | Luxembourg | Yes* | Yes* | Yes* |
| Andorra | Yes* | Yes* | Yes* | | | | |
| Armenia | | | | Malta | * | * | * |
| Austria | No | No | - | Republic of Moldova | | | |
| Azerbaijan | Yes | - | - | Netherlands* | No* | No* | No* |
| Belgium | Yes* | Yes* | Yes | Norway | No* | ı | ı |
| Bosnia & Herzegovina | N/A | N/A | N/A | Poland | Yes* | Yes* | Yes* |
| Bulgaria | | | | Portugal | Yes* | Yes* | Yes* |
| Croatia | No* | No* | No* | Romania | | | |
| Cyprus | -* | -* | -* | Russian Federation | Yes/ No* | Yes/ No* | Yes/ No* |
| Czech Republic | Yes* | Yes* | Yes* | San Marino | | | |
| Denmark** | Yes and No* | Yes and No* | Yes | Serbia | Yes | Yes | Yes |
| Estonia | Yes | Yes | Yes | Slovakia | Yes | Yes | Yes |
| Finland | No* | No* | No* | Slovenia | Yes* | Yes* | - |
| France | Yes | Yes | Yes | Spain | Yes | Yes | Yes |
| Georgia | No* | No* | No* | Sweden | No | No | N/A |
| Germany | No* | 1 | - | Switzerland | No | ı | ı |
| Greece | Yes* | Yes* | Yes* | "FYROM" | - | 1 | ı |
| Hungary | Yes and No | Yes and No | Yes | Turkey | No | No | No |
| Iceland | Yes* | Yes* | - | Ukraine | Yes* | Yes* | Yes* |
| Ireland | No* | No* | No* | United Kingdom | No* | No* | No* |
| Italy | Yes* | Yes* | No* | Canada | * | * | * |
| Latvia | Yes | Yes | Yes | Israel | Yes | Yes | - |
| Lithuania** | Yes* | Yes* | Yes* | | | | |

Andorra

Specify the legal provisions. Law 12/2019, of the 15th February, described as techniques of assisted reproduction

Belgium

In the case of gametes, anonymity is the rule. The law does, however, allow non-anonymous donations if they are based on an agreement between the donor and the recipient or recipients.

Croatia

After reaching the age of 18 a person born from the MAP procedure is allowed to have access to data on identity of biological parent(s).

Cyprus

There is no indication for the practice followed by several clinical centers, due to the non-existence of relevant legislation.

Czech Republic

According to the Czech Act on Specific Health Services (Act No. 373/2011 Sb.)

Denmark

Donor of oocytes can be anonymous or non-anonymous.

Donor of sperm can be anonymous or non-anonymous.

Finland

Donations are coded. The competent authority keeps a donation register on the donations of gametes and embryos for the purposes of MAP.

If a child born using MAP wishes to know the donor's identity, he or she will have access to the information after having turned 18 years of age.

Georgia

LHC: no specific provisions are included in the LHC on this issue.

*DL-RHRR:

Donation of gametes and embryo is not anonymous; however information on the identity of a gamete donor is confidential. Also, any personal data collected about a couple or single women applying for MAP is confidential.

United Register of Gamete Donors will include data about the identity of gamete donors as well as of couple.

These data are confidential. However, the law may make exceptions for specific cases; e.g. "when the disclosure of information on the donor's genetic characteristics is necessary for the health purposes of the child, born as a result of medically assisted reproductive technologies".

Germany

With regard to the question of whether sperm donations for MAP purposes may remain anonymous, recourse is made to the ruling of the Federal Constitutional Court which states that the general right of personality (Art. 2 (1) in conjunction with Art. 1 (1) of the Basic Law) also applies to the right of the child to have knowledge of his/her parentage (consistent past decisions since the Federal Constitutional Court decision of 31 January 1989 - 1 BvL 17/87 - BVerfGE 79, 256). Therefore, the physician who oversees the sperm donation must ensure that the child will later on be able to find out who his/her father is. Anonymising the sperm donation or the use of pooled sperm for artificial fertilisation is not permissible. According to the Model Guidelines of the German Medical Association on the performance of assisted reproduction, the physician must inform the sperm donor that he/she is required to disclose the name of the donor to the child on request and cannot, in this regard, invoke medical confidentiality.

On 28 January 2015, the Federal Court of Justice (file no. XII ZR 201/13) ruled that children have the right to ask the treating reproductive health physician or sperm bank to disclose the name of the sperm donor from the medical treatment agreement between the parents and the clinic.

Greece

The law adopts the principle of anonymity regarding any donation, therefore, the identity of the donor cannot be revealed under any circumstances.

According to Art 8, para 6 of the new law, medical information that concerns the donor are kept in an anonymous codified form in the Cryopreservation Bank and in the National Registry of Donors and Receivers.

Iceland

See art.18 reg.568/1997 (If a donor wishes to remain anonymous, health workers are obliged to ensure that this is respected. In this case, the donor may neither receive information about the couple receiving the donated gamete or the child, nor the couple or the child receive information about the donor. If a donor does not wish to remain anonymous, the institution shall preserve information about him in a special file. If the donation of gamete leads to the birth of a child, information about the child and the couple who received the gamete shall be kept in the same file. A child born on account of a gamete donation where the donor does not wish to remain anonymous can at the age of 18 gain access to a file pursuant to paragraph 2 for the purpose of obtaining information about the identity of the donor. If a child receives information about the gamete donor at the institution, the said institution shall as soon as possible inform the donor that the information has been given.)

Ireland

As previously indicated, under the Children and Family Relationships Act gamete and embryo donation is permitted on a non-anonymous basis. Gamete and embryo donors will be required to provide name; place and date of birth; nationality, place and date on which s/he provided the donation; and contact details. Once a donor-conceived child has attained the age of 18 years s/he may request the name, date of birth and contacts details of the relevant donor, as recorded in the National Donor-Conceived Person Register.

Lithuania**

All personal information related to the gamete recipient, gamete donor or the child, conceived during MAP using donor's gametes, is confidential. However, a court may permit disclosure of information about the donor(s) and children if this information is necessary for the child's or the donor's health or for any other valid reasons. When a child born using ART procedures reaches 18 years of age, the donor's identity may also be disclosed with the latter's consent.

Luxembourg

This depends on the legislation of the countries from which the donations originate.

Malta

There are no legal provisions.

Netherlands

The law requires professionals who carry out the MAP, to provide data about the donor(s) to a national registration.

Norway

Sperm donors cannot be anonymous.

Poland

Lack of specific legal provisions on the subject.

Anonymity of donations is a matter of medical confidentiality. The Opinion of the Polish Association of Obstetricians recommends double anonymity (of both the donor and the receiver). Clinics' internal regulations may provide otherwise.

Portugal

Most of Portuguese bioethicists – including the Portuguese National Bioethical Council – have defended that anonymous donation should finish, like what happened in the UK, in order to protect the child rights to identity, information and health

Russian Federation

It may be either anonymous or non-anonymous with regard to sperm, oocytes and embryos.

Slovenia

Art. 18 specifies the rules of confidentiality regarding both the couples receiving MAP and the gamete donors.

Ukraine

It is permitted by law (Section I).

United Kingdom

Due to amendments to the Human Fertilisation and Embryology Act – the law overseeing the use of fertility treatment in the UK – donor conceived people born after 1 April 2005 can request identifying information about their donor from the HFEA once they reach 18 years old. This, however, means that there are different information access rights depending on when the donor conceived person was conceived. These are set out below.

Conceived before 1 August 1991:

The HFEA is required by law to keep a Register of information which records details of regulated assisted reproductive treatment services in the UK. The HFEA has recorded this information since 1 August 1991, which is the date the Human Fertilisation and Embryology Act 1990 came into force. The Register contains all births resulting from treatment services, including those where donated gametes were used. The Register also records information regarding gamete donors, including a physical description, ethnicity and any additional information they wish to provide, for example occupation and interests. Since donor anonymity was removed in April 2005, the Register also records the donor's name and address. Donors who donated prior to April 1 2005 can elect to remove their anonymity retrospectively.

There may be opportunities for some people conceived through donation before 1991 to find information about their donor and donor-conceived genetic siblings.

However, before the HFEA was set up in 1991, there was no central repository of donor information. This means that people conceived before this date are likely to have much more difficulty tracing their donor. The Donor Conceived Register was set up on 1 April 2013 to replace the UK Donor Link (UKDL) and facilitates contact between donors and their donor-conceived children conceived before 1 August 1991. Those affected by donation before 1 August 1991 are able to sign up to a contact register.

Conceived between 1 August 1991 – 31 March 2005:

People conceived following donor conception before the law changed in 1 April 20015 cannot access identifying information about their donor.

However, donor conceived people who are over 16 years old, are able to apply to the HFEA to find the anonymous information their donor provided.

There is the small possibility they can make contact with their donor, once they reach 18 years old. This is only if their donor 're-registered' at their clinic or with the HFEA and provided current contact details.

Further information is provided on the HFEA website:

https://www.hfea.gov.uk/donation/donors/#

Conceived on or after 1 April 2005:

In 2005, the laws around donor information access changed. The law change meant that everyone who donated sperm or eggs after 1 April 2005 is identifiable to children born as a result of their donation, once the child is 18 years old. This means that, if requested, contact details can be passed on to people born as a result of their donation. Their last known address, date of birth and name is provided to people born as a result of their donation, when they apply to the HFEA for information.

The reason anonymity has been removed was because it was recognised by law that many donor-conceived people have a desire and an interest in finding out about where they came from. Similarly the interest donors have in finding out anonymous information about children born from their donation has been recognised.

The HFEA also has a sibling register, to allow donor-conceived individuals to make contact with their donor-conceived siblings, from the age of 18, on the basis of mutual consent.

When a donor-conceived person reaches the age of 18, they can choose to place their contact details on a voluntary sibling contact register called Donor Sibling Link, administered by the HFEA. The HFEA will facilitate the exchange of contact details between siblings who consent to be on this register.

Consequently, it will be possible for donor-conceived adults to trace their siblings, on the basis of mutual consent, through the voluntary sibling contact register. It is not possible for parents, however, to trace their child's siblings through the voluntary contact sibling register.

Further information is provided on the HFEA website: https://www.hfea.gov.uk/i-am/donor-conceived-people-and-their-parents/

Canada

Pursuant to section 14 of the Act, which has yet to come into force, a licensee shall not accept the donation of human reproductive material or an *in vitro* embryo unless the licensee has collected the required health reporting information from the donor, which will be set out in the regulations. As defined in the Act, health reporting information can include the identity of the donor. Therefore, to the licensee who accepts a donation of human reproductive material or an in vitro embryo, the donation will likely not be anonymous.

However, section 15 of the Act, which has yet to come into force, states that licensees are not permitted to disclose health reporting information (which may include identity) for any purpose except with the written consent of the person to whom the information relates. Therefore, if a donor does not provide written consent to disclose his or her identity, the licensee is not permitted to disclose the information to anyone, including the recipient or the resulting child. Some limited exceptions to disclosure do exist, but not with respect to disclosure to recipients or resulting children. On the other hand, if a donor provides written consent for the purpose of disclosure to a recipient or resulting child, the licensee may disclose the health reporting information. Consequently, whether or not the identity of the donor is disclosed depends on whether written consent to do so was obtained.

- 17. Is it possible to obtain information about the biological origin of a child born after gametes or embryo donation?
 - i. For the child him or herself
 - ii. For the parents
 - iii. For a court

| Country | i | ii | iii | Country | i | ii | iii |
|-------------------------|------|------|------|-----------------------|------|------|------|
| Albania | | | | Luxembourg | - | - | - |
| Andorra | Yes | No | - | | | | |
| Armenia | | | | Malta** | -* | -* | -* |
| Austria | Yes* | Yes* | Yes* | Republic of Moldova | | | |
| Azerbaijan | - | - | - | Netherlands | Yes | No | Yes |
| Belgium | No* | No* | Yes* | Norway | Yes* | No | No |
| Bosnia & Herzegovina | - | - | - | Poland | No* | No* | No* |
| Bulgaria | | | | Portugal | No | No | Yes |
| Croatia | Yes* | No* | Yes* | Romania | | | |
| Cyprus | _* | _* | _* | Russian Federation | No* | Yes | Yes |
| Czech Republic | Yes* | Yes* | Yes* | San Marino | | | |
| Denmark** | Yes* | No | No | Serbia | Yes | Yes | Yes |
| Estonia | Yes | No | No | Slovakia | No | No | Yes |
| Finland | Yes* | Yes* | No* | Slovenia | No | No | Yes* |
| France | No* | No* | No* | Spain | Yes | Yes | Yes |
| Georgia | Yes* | Yes* | Yes* | Sweden** | Yes | No | No |
| Germany | Yes | No | No | Switzerland | Yes | No | Yes* |
| Greece | Yes* | Yes* | Yes* | "FYROM" | - | - | - |
| Hungary | Yes* | - | - | Turkey | No | No | No |
| Iceland | Yes* | No | No | Ukraine | No | No | Yes |
| Ireland* | Yes* | Yes* | - | United Kingdom | Yes* | No* | Yes* |
| Italy | - | - | - | Canada | Yes* | Yes* | Yes* |
| Latvia | No | No | Yes | Israel | No | No | Yes |
| Lithuania** | No* | No | Yes* | | | | |

<u>Austria</u>

Details § 20 Law on Medical Assisted Procreation "Fortpflanzungsmedizingesetz".

Belgium

- i) no*; ii) no* The law provides that once supernumerary embryos or gametes have been implanted, the parentage rules set out in the Civil Code operate in favour of the author or authors of the parental project. No parentage suit may be filed against the donor by the recipient or by the child born through the use of supernumerary embryos or gametes.
- **iii)** There are no specific legal provisions that would apply to the courts in this area. It cannot be ruled out that a court might obtain information about the biological origin of a child born through gamete or embryo donation if it deemed this necessary.

Croatia

After reaching the age of 18, person born from the MAP procedure is allowed to have access to data on identity of biological parent(s).

Parents do have a right to access the donor data in the case of medical indication.

Both, child and parents should require data access from the MAP Registry.

Cyprus

There are no legal provisions.

There is no indication for the practices followed by the IVF centers, due to the non-existence of relevant legislation.

Czech Republic

Only some very basic health, psychosocial and appearance information.

Denmark

It's only possible to obtain information if the sperm donor or oocyters donor is non-anonymous. Identity of the donor can be obtained when the child are 18 years or older.

Finland

If a child born using MAP wishes to know the donor's identity, he or she will have access to the information after having turned 18 years of age.

When MAP has been provided for a woman not living in marriage or in a relationship comparable to marriage with a partner of the opposite sex (after 1 April 2019: a woman not living in marriage, registered partnership or in a relationship comparable to them, regardless of whether the partner is same sex or opposite sex) and the donor has given his consent to being confirmed as the father of the child, the mother and the child are entitled to learn from the service provider the donor's code and, by providing the donation register with the code, the identity of the donor. According to the Code of Judicial Procedure, the court does not have access to sensitive health care data unless the person in whose benefit the secrecy obligation has been provided consents to it or he or she is deceased and if very important reasons require it. Exception to this rule is a case where the prosecutor has brought charges for an offence for which the maximum sentence is imprisonment for at least six years.

France

The law makes provision solely for the treating physician, in the event of a therapeutic necessity, to have access to non-identifying medical information concerning a child conceived by gamete donation.

Hungary

Detailed provisions in Act § 179 (1)

Georgia

LHC: no specific provisions are included in the LHC on this issue.

The answers given to question 17 are based on DL-RHRR.

Germany

There are no explicit legal provisions.

Children have the right to ask the treating reproductive health physician or sperm bank to disclose the name of the sperm donor from the medical treatment agreement between the parents and the clinic (cf. answer to question 16).

Greece

The child and his legal representative may have access only to medical data which are kept in secrecy and in a codified form in Cryopreservation Banks.

Law 2472/1997 on the "Protection of individuals with regard to the processing of personal data" qualifies health data as "sensitive" kind of information and stipulates special permission of the Data Protection Authority (Article 7).

According to Art 20, para 3 of Law 3305, access to the National Registry of Donors and Receivers is permitted only to the child and for reasons related to his health, with the permission of the Data Protection Authority and as long as the conditions of Law 2472/1997 regarding protection of personal data are fulfilled. The parents may have access to information only when they act as representatives of the child. The Court may order access.

Iceland

The child cannot obtain information if the donor has wished to remain anonymous, See art.18 reg.568/1997.

Ireland

According to the Children and Family Relationships Act 2015, a donor-conceived child who has attained the age of 18 years, or the parent of a donor-conceived child who has not attained the age of 18 years, may request the following information from the Register:

- (a) information other than the relevant donor's name, date of birth and contact details, that is recorded on the Register in respect of the relevant donor;
- (b) the number of persons who have been born as a result of the use in a donor-assisted human reproduction procedure of a gamete donated by the relevant donor, and the sex and year of birth of each of them.

In addition, the Act provides that, a donor-conceived child who has attained the age of 18 years may request the name, date of birth and contacts details of a relevant donor, as recorded in the Register. The donor must be issued with a notice informing him or her that a request has been made by the donor-conceived child. The requested information may be released 12 weeks from the date on which on which the notice is sent (with very restrictive exceptions).

Lithuania**

Personal information related to the gamete recipient, gamete donor or the child, conceived using donor's gametes, is confidential. However, a court may permit disclosure of information about the donor(s) and children if this information is necessary for the child's or the donor's health or for any other valid reasons. When a child born using ART procedures reaches 18 years of age, the donor's identity may also be disclosed with the latter's consent.

Malta

There are no legal provisions

Norway

Children born after sperm donation have the right to know the identity of their donor when they (the children) reach the age of 18.

Poland

There are no specific legal provisions on the subject.

Doctors are therefore bound by medical confidentiality in respect of both the donor and the receiver of the gametes. Information concerning the donor may be revealed only on medical grounds, when the life or health of the child is threatened.

Russian Federation

As to the child, regulation is uncertain. It may be argued that because a child has the right to consent to medical treatment from 15 years of age, he/she may also have the right to obtain information about his/her biological origin when the child reaches 15 years of age. But, to repeat, there is no clear regulation on this matter.

Slovenia

Art. 18: The child may request medically important information about the donor after reaching 15 years of age, provided that he/she is mentally competent. The child's legal representative may be given such information only with a permission issued by court, in cases of exceptionally important medical reasons.

The child's physician has the right to access information in the donors' registry for health reasons.

The court and administrative body have a right to access information in the registry if that is absolutely necessary for carrying out their official duties under this law.

Sweden

- Yes, by request to the clinic which has a special registry about the donors (to be saved for 70 years). For embryo donor children it will be possible to find genetic siblings who have requested to be entered into the register.
- ii. No.

iii. Unlikely, but potentially if court rules it necessary.

Switzerland

iii. if necessary

United Kingdom

The HFE Act 1990 (as amended) allows donor conceived people to apply for non-identifying information about the donor, if available, such as family medical history, hair/eye colour and interests, when they reach 16. If they were conceived after 1 April 2005, when the donor conceived person reaches 18 years old, they may apply to the HFEA to receive identifying information about their donor.

Parents of children conceived through donor conception can access non identifying information about the donor from the HFEA.

Section 34 of the HFE Act 1990 permits the Authority to make disclosure where it is necessary for the purposes of instituting proceedings under the Congenital Disabilities Act.

<u>Ca</u>nada

As defined in the Act, health reporting information can include "the identity, personal characteristics, genetic information and medical history of donors of human reproductive material and *in vitro* embryos, persons who have undergone assisted reproduction procedures and persons who were conceived by means of those procedures."

One of the roles of the Assisted Human Reproduction Agency of Canada will be to collect health reporting information from fertility clinics for its information registries. Regulations will be developed to determine what information is to be provided to the Agency by the fertility clinics for the information registries.

In particular, the questionnaire asks whether it is possible to obtain identifying and non-identifying information about the donor. Once the relevant provisions are in force, the Act will ensure that, in cases where sperm, eggs or *in vitro* embryos are used, individuals undergoing treatment will be provided with the donor's non-identifying health reporting information. Moreover, the Act provides that a person born using donated sperm, eggs or *in vitro* embryos, may request the disclosure of all non-identifying health reporting information relating to the donor. However, in accordance with the Act, identifying information will not be released to offspring, donors, or individuals undergoing procedures except with the written consent of the person to whom it relates.

The Act only refers to the release of health reporting information, which encompasses a wide range of information. The disclosure of other information not included in the definition of health reporting information to persons born using donated sperm, eggs or *in vitro* embryos is not addressed in the Act.

The disclosure of health reporting information for any purpose by a licensee will be prohibited under the Act, except in specific instances. For example, a licensee must disclose health reporting information for the purpose of complying with a subpoena or warrant issued or order made by a court, body or person with jurisdiction to compel the production of information or for the purpose of complying with rules of court relating to the production of information.

In addition, the Assisted Human Reproduction Agency of Canada, described above, must disclose health reporting information for the purposes of complying with a subpoena or warrant issued or order made by a court, body or person with jurisdiction to compel the production of information, or for the purposes of complying with rules of court relating to the production of information.

In particular:

- a. Identity of the donor(s)
- i. For the child him or herself
- ii. For the parents
- iii. For a court

| Country | a.i | a.ii | a.iii | Country | a.i | a.ii | a.iii |
|-------------------------|------|------|-------|------------------------|------|------|-------|
| Albania | | | | Luxembourg | - | - | - |
| Andorra | Yes | No | - | | | | |
| Armenia | | | | Malta | - | - | - |
| Austria | Yes | Yes* | Yes | Republic of Moldova | | | |
| Azerbaijan | - | - | - | Netherlands | Yes | No | Yes |
| Belgium | No* | No* | Yes | Norway | Yes | No | No |
| Bosnia & Herzegovina | ı | ı | ı | Poland | No* | No* | No* |
| Bulgaria | | | | Portugal | | | |
| Croatia | 1 | ı | ı | Romania | | | |
| Cyprus | - | - | - | Russian Federation | No | No | Yes* |
| Czech Republic | No | No | Yes | San Marino | | | |
| Denmark** | Yes | No | No | Serbia | Yes | Yes | Yes |
| Estonia | No | No | No | Slovakia | No | No | Yes |
| Finland | Yes* | Yes* | No* | Slovenia | No | No | Yes* |
| France | -* | -* | -* | Spain | Yes | Yes | Yes |
| Georgia | No | No | No | Sweden | Yes | No | No |
| Germany | Yes | No | No | Switzerland | Yes | No | Yes* |
| Greece | No | No | No | "FYROM" | - | - | ı |
| Hungary | Yes* | - | - | Turkey | No | No | No |
| Iceland | Yes* | No | No | Ukraine | - | - | Yes |
| Ireland | Yes* | Yes* | - | United Kingdom | Yes | No | Yes |
| Italy | - | - | - | Canada | Yes* | Yes* | Yes* |
| Latvia | No | No | Yes | Israel | No | No | No |
| Lithuania | Yes* | Yes* | Yes* | | | | |

<u>Austria</u>

Details § 20 Law on Medical Assisted Procreation "Fortpflanzungsmedizingesetz".

Belgium

The fertility centre is legally bound to render inaccessible any data that could be used to identify the embryo or gamete donor. Anyone working for or in a fertility centre who becomes aware of information that could be used to identify the donor is subject to the professional secrecy requirement (Art. 458 of the Criminal Code). Non-anonymous gamete donations are permitted, however, if they are based on an agreement between the donor and the recipient or recipients.

Finland

See answer to previous question.

France

See answer to previous question.

Hungary

See answer to previous question.

Germany

There are no explicit legal provisions. The child's claim in respect of a) is based on the child's right to know about his or her biological origin (see response to question 16). However, this right does not give rise to any – further-reaching – claim to disclosure of certain health information concerning the donor.

Unlike the child, the (social) parents are, in principle, not entitled to learn the identity of the sperm donor. Pursuant to the data protection provisions under the Transplantation Act, the sperm donor and the (social) parents are to remain anonymous to one another.

In case of litigation, courts have to decide on the above-mentioned rights; however, the courts themselves are not intrinsically entitled to request information about the parentage of a child.

Greece

The law adopts the principle of anonymity regarding any donation, therefore, the identity of the donor cannot be revealed under any circumstances. The child and his legal representative may have access only to medical data which are kept in secrecy and in a codified form in Cryopreservation Banks.

Iceland

The child cannot obtain information if the donor has wished to remain anonymous, See art.18 reg.568/1997.

Ireland

See answer to previous question.

Lithuania

See commentary to the question No. 17.

Poland

See comment to first table answer 17.

Russian Federation

There are no provisions in this regard, but under general rules of court proceedings it must be possible for a court to get any information that the court needs, including that about the donor.

Slovenia

See comment to first table answer 17.

Switzerland

iii. if necessary

Canada

See comment to first table answer 17.

b. Certain health information concerning the donor(s)

- i. For the child him or herself
- ii. For the parents
- iii. For a court

| Country | b.i | b.ii | b.iii | Country | b.i | b.ii | b.iii |
|-------------------------|------|------|-------|------------------------|------|------|-------|
| Albania | | | | Luxembourg | - | - | - |
| Andorra | Yes | No | - | | | | |
| Armenia | | | | Malta | -* | _* | _* |
| Austria | Yes* | Yes* | Yes* | Republic of Moldova | | | |
| Azerbaijan | - | - | - | Netherlands | Yes | Yes | Yes |
| Belgium | Yes* | Yes* | Yes | Norway | No | No* | No |
| Bosnia & Herzegovina | - | - | - | Poland | No* | No* | No* |
| Bulgaria | | | | Portugal | | | |
| Croatia | Yes | Yes | Yes | Romania | | | |
| Cyprus | -* | -* | -* | Russian Federation | Yes* | Yes | Yes |
| Czech Republic | Yes | Yes | Yes | San Marino | | | |
| Denmark | No | No | No | Serbia | Yes | Yes | Yes |
| Estonia | Yes | Yes | Yes | Slovakia | Yes | Yes | Yes |
| Finland | No | No | No | Slovenia | Yes* | Yes | Yes* |
| France | -* | -* | -* | Spain | Yes | Yes | Yes |
| Georgia | Yes* | Yes | Yes | Sweden | Yes* | No | No |
| Germany | No | No | No | Switzerland | No* | No* | No* |
| Greece | Yes | Yes | Yes* | "FYROM" | - | - | - |
| Hungary | -* | - | - | Turkey | - | - | - |
| Iceland | Yes* | No | No | Ukraine | - | - | Yes |
| Ireland* | -* | -* | -* | United Kingdom | Yes | Yes | Yes |
| Italy | Yes | Yes | - | Canada | Yes* | Yes* | Yes* |
| Latvia | Yes | Yes | Yes | Israel | No | No | Yes |
| Lithuania** | Yes* | Yes* | Yes* | | | | |

<u>Austria</u>

Details § 20 Law on Medical Assisted Procreation "Fortpflanzungsmedizingesetz".

Belaium

Medical information concerning the two supernumerary embryos or gamete donor, which may be of importance for the healthy development of the unborn child, may be communicated by the fertilization center to the receiving party or to the receiving couple, who ask for it when taking a decision, as well as to the treating physician of the conceived child when the state of his/her health requires it.

Cyprus

See comment to first table answer 17.

France

See answer to first table of question 17.

Hungary

See answer to first table of question 17.

Georgia

Health data of the gamete donor, particularly information about the donor's genetic characteristics, could be disclosed from the register of gamete donors if this is necessary for the health purposes of the child, born as a result of MAP.

Germany

There are no explicit legal provisions.

In case of litigation, courts have to decide on the above-mentioned rights; however, the courts themselves are not intrinsically entitled to request information about the parentage of a child.

Greece

The child or the parents (acting as representatives of the child) can have access to health information which are kept in secrecy and in a codified form in Cryopreservation Banks but not to the identity of the donor. The Court also may authorize access to health information.

Iceland

The child cannot obtain information if the donor has wished to remain anonymous, See art.18 reg.568/1997.

Ireland

Under the proposed assisted human reproduction legislation, medical information relating to the donor may be released to a medical practitioner in order to avoid an imminent and serious risk to the health of a person or to enable the medical practitioner to provide medical advice to a person regarding the existence of a genetic or hereditary condition.

Lithuania

See commentary to the question No. 17

Malta

See commentary to first table answer 17.

<u>Norway</u>

For donors recruited in Norway, the parents will be familiar with the general criteria for selection of a donor (good physical and mental health, no serious inheritable disease; as well as the test regimes) but will not have any other information about the donor. Norway allows import of sperm from spermbanks established outside of Norway, but only if they can provide sperm from open donors, and in conformity with the relevant EC directives.

Poland

See comment to first table answer 17.

Russian Federation

For a child – only after the child reached 15 years of age (when a child requires the right to consent to medical treatment).

Slovenia

See comment to first table answer 17.

Sweden

Yes, if relevant and noted in the donor registry.

<u>Switzerland</u>

i, ii, iii: except in life saving situations.

Canada

See comment to first table answer 17.

c. Other information

- i. For the child him or herself
- ii. For the parents
- iii. For a court

| Country | c.i | c.ii | c.iii | Country | c.i | c.ii | c.iii |
|-------------------------|------|------|-------|------------------------|------|------|-------|
| Albania | | | | Luxembourg | -* | -* | -* |
| Andorra | | | | | | | |
| Armenia | | | | Malta | -* | -* | -* |
| Austria | No | No | No | Republic of Moldova | | | |
| Azerbaijan | - | - | - | Netherlands | Yes | Yes* | Yes |
| Belgium | No* | No* | Yes | Norway | Yes* | No | No |
| Bosnia & Herzegovina | ı | ı | - | Poland | No* | No* | No* |
| Bulgaria | | | | Portugal | | | |
| Croatia | Yes | No | Yes | Romania | | | |
| Cyprus | * | -* | _* | Russian Federation | No | Yes | Yes |
| Czech Republic | Yes* | Yes* | Yes* | San Marino | | | |
| Denmark | No | No | No | Serbia | Yes | Yes | Yes |
| Estonia | No | No | No | Slovakia | No | No | No |
| Finland | No* | No* | No* | Slovenia | No | No | Yes* |
| France | -* | -* | -* | Spain | No | No | No |
| Georgia | 1 | Yes* | - | Sweden | Yes* | No | No |
| Germany | No* | No* | No* | Switzerland | No | No | No |
| Greece | No | No | No | "FYROM" | - | 1 | - |
| Hungary | ı | ı | - | Turkey | - | ı | - |
| Iceland | Yes* | No | No | Ukraine | No | No | Yes |
| Ireland | - | 1 | - | United Kingdom | Yes | Yes | Yes |
| Italy | - | - | - | Canada | -* | -* | -* |
| Latvia | - | - | - | Israel | No | No | Yes |
| Lithuania** | Yes* | Yes* | Yes* | | | | |

Belgium

The law requires the centre to record certain data relating to the donor, including the physical characteristics of both embryo providers or of the gamete donor. The law only allows the parents and child access to such medical data as are necessary for the child's health, however.

Cyprus

(See commentary to first table answer 17).

Czech Republic

No exact legal framework for that.

Finland

Only limited information may be registered. Donors undergo a health examination in order to rule out serious diseases that may constitute a health risk to a future child. No specific health information concerning the donor is recorded.

<u>France</u>

See answer to first table of question 17.

Georgia

A couple or a single woman has the right to request and receive information on the donor's age, appearance, ethnic background, and health condition.

- Obligation of gamete donor to provide information about his/her health:
 According to the DL-RHRR gamete donors are obligated "to give the medical personnel complete and comprehensive information on his/her health condition prior to gamete donation."
- Right of the gamete donor to receive information about his/her health:
 According to the DL-RHRR gamete donors are entitled to receive "information concerning his/her own health, which may be discovered as a result of monitoring the child born after utilizing assisted reproductive technologies."

Germany

There are no explicit legal provisions.

In case of litigation, courts have to decide on the above-mentioned rights; however, the courts themselves are not intrinsically entitled to request information about the parentage of a child.

Iceland

The child cannot obtain information if the donor has wished to remain anonymous, See art.18 reg.568/1997.

Lithuania

See commentary to the question No. 17.

Luxembourg

This depends on the legislation of the countries from which the donations originate.

Malta

(See commentary to first table answer 17).

Netherlands

Parents can obtain information about physical characteristics, education and profession and medical issues.

Norway

At the age of majority, the child can obtain information about the identity of the donor (name and address according to the national registry). This is the only information that will be provided.

Poland

(See comment to first table answer 17).

Slovenia

(See comment to first table answer 17).

Sweden

Contact info and any other info provided in the medical file

A donor child has the right to, at a "mature age" (interpreted as appx 18) and upon request, find out the identity and contact information of their donor. This information is to be kept for 70 years in a special donor registry. The parents are encouraged to inform their child about the donation.

<u>Ca</u>nada

(See comment to first table answer 17).

18. Is it possible to contest maternity and paternity of children born utilising MAP and under which conditions (family law provisions)?

| Country | Reply | Country | Reply |
|---------------------------|--------------------|-----------------------|-------|
| Albania | | Luxembourg | No* |
| Andorra | No | | |
| Armenia | | Malta | - |
| Austria | Yes* | Republic of Moldova | |
| Azerbaijan | No | Netherlands | No |
| Belgium | No* | Norway | Yes* |
| Bosnia and Herzegovina | - | Poland | * |
| Bulgaria | | Portugal | |
| Croatia | Yes* | Romania | |
| Cyprus | - | Russian Federation | No* |
| Czech Republic | No* | San Marino | |
| Denmark | Yes* | Serbia | - |
| Estonia | No | Slovakia | No |
| Finland | Yes* | Slovenia | No* |
| France | No | Spain | No |
| Georgia | -* | Sweden | No |
| Germany | * | Switzerland | No |
| Greece | Yes* | "FYROM" | 1 |
| Hungary | No with exception* | Turkey | No* |
| Iceland | No* | Ukraine | Yes |
| Ireland | Yes/No* | United Kingdom | Yes* |
| Italy | No* | Canada | Yes* |
| Latvia | No | Israel | No* |
| Lithuania* | -* | | |

Austria

Under Austrian law, the mother is the woman who gave birth to the child. The father is the husband of the mother, or the man who recognized paternity or whose fatherhood was imposed by the court. The donor of sperm/eggs is excluded by law from fatherhood/motherhood.

Regulations see § 144 and §145 Austrian Civil Code "Allgemeines Bürgerliches Gesetzbuch"

<u>Belgium</u>

The law states that once supernumerary embryos or gametes have been implanted, the parentage rules laid down in the Civil Code operate in favour of the authors of the parental project.

No lawsuit relating to parentage or to its effects on property rights may be brought by donors of supernumerary embryos or gametes.

Croatia

Contest is regulated within the Family Law. It is possible to contest maternity or paternity only in the cases when MAP procedure was performed without consent.

Czech Republic

According to the Civil Code, the mother is the woman who gave birth to the child and the father who agreed with the treatment.

Denmark

A father or a co-mother can contest paternity or co-maternity if he or she believes that the child is not conceived by the MAP he or she gave consent to, but instead is conceived by a sexual relationship.

Finland

According to Paternity Act (*isyyslaki*; 11/2015) the man having consented to MAP will be the father of the child born through MAP. According to Maternity Act (entering into force 1 April 2019) the same applies to a woman in a female couple. If sperm is used to provide MAP to a single mother, the donor can consent to potentially be declared as the father of a future child. If the sperm donor has consented only to fertility treatments and not to paternity, he cannot be declared the father of the child.

Hungary

The assumption of paternity cannot be contested by the father, with the exception if the husband or common-law companion has not consented to the MAP process (Civil Code § 4:108 a)).

The donor of sperm or embryo is excluded by law from fatherhood (Civil Code § 4: 103 (5)).

The donor of oocyte or embryo is excluded by law from motherhood (Civil Code § 4: 115 (4). The woman delivering the child is considered the mother.

Georgia

There are no specific provisions on this subject in family law at present.

Germany

German law does not provide for maternity to be challenged. A child's mother is - also where MAP has been used - the woman who has given birth to him/her (section 1591 Civil Code). By contrast, it is in principle possible to challenge the paternity of children born as a result of assisted reproduction (sections 1599 ff. Civil Code). The persons entitled to do so are the father, the man who declares in lieu of an oath that he had sexual intercourse with the mother of the child during the period of conception, the mother and the child (section 1600 (1) Civil Code). However, any challenge to paternity by the father and the mother is excluded if they have both agreed to the artificial fertilisation (section 1600 (5) Civil Code).

Greece

Contestation of maternity and paternity: contestation of paternity is not allowed when the father has provided consent at the beginning of the treatment.

Also, according to Law 3089/02, consent before a notary public of a man and a woman living in a free union takes place in order to guarantee their affiliation with the child to be born. As a result of that, contestation of the voluntary affiliation is forbidden.

In the case of surrogate motherhood, according to the law, the woman to whom the Court's approval has been given is considered to be the legal mother of the child. Exceptionally, either the commissioning, or the surrogate mother, may contest this in Court, under conditions provided for by the law.

<u>Iceland</u>

See art.6, Act in respect of Children, no. 76/2003 (A man who has agreed that his wife be artificially inseminated according to the Act on is deemed to be the father of a child so conceived. The same applies to a man and a woman who have registered their cohabitation with the National Registry. - A man who donates sperm for the purpose of it being used in artificial insemination a woman other than his wife or cohabiting spouse, cf. paragraph 1, according to the provisions of the Act on Artificial Insemination will not be deemed to be the father of a child conceived with his sperm. -A man who donates sperm for another purpose than stipulated in paragraph 2 is deemed to be the father of a child conceived with his sperm unless the sperm is used without his knowledge or after his decease.)

Ireland

According to the Irish Constitution, the woman who has given birth to a child is always regarded as the legal mother. This assertion was challenged in the Irish Courts, but it was upheld in the Supreme Court in 2014 in the *MR* and *Anor* – *v- An tArd Chlaraitheoir* & *Ors* (Surrogacy) case.

According to the Children and Family Relationships Act 2015, the parents of a donor-conceived child are the mother and her husband, civil partner or cohabitant as the case may be. A donor of a gamete or embryo is not regarded as the parent of a donor-conceived child.

Italy

In the case of reproduction using a heterologous donor - even if prevented by law - the donor cannot disown the child (Art 9). The mother of the child after MAP cannot declare her wish not to be entered in the birth registers as provided for by dpr no 396 (2000).

Lithuania*

Contesting of maternity/paternity in the context of the MAP is not specified in the current Law on MAP of the Republic of Lithuania.

Luxembourg

See Art.312 of the Civil Code cited in the section I – relevant instruments or draft instruments.

Norway

- a child or a parent, as well as a third person who claims paternity of a child with another legal father may contest paternity in front of a court. There is no exception for children or parents of children born after MAP, but a sperm donor <u>cannot</u> contest paternity of a child born after MAP procedures using donated sperm.
- the donor has no legal responsibility for the child, and has no right to any information about children that have been born using his sperm (except for the maximum number).
- according to Norwegian family law provisions, the legal father of a child conceived after MAP is the one the mother is married to at birth ("pater est"). If the woman is not married, the legal father will be the man who acknowledge paternity for the child.

Poland

There is no specific legal provisions on the subject.

Under the general laws governing descent, it is not possible to contest paternity in the event of homologous insemination within a married couple.

In cases of heterologous insemination, however, paternity may be contested, but only if the spouse of the inseminated woman did not consent to insemination with another man's sperm.

Relevant provisions:

Presumption of paternity:

Art. 62 of the Code of the Family and Guardianship:

- "1. A child born in wedlock or within three-hundred days of the dissolution or annulment of the marriage shall be presumed to be the child of the mother's husband.
- 2. A child born within three-hundred days of the dissolution or annulment of the marriage, but after the mother has remarried, shall be presumed to be the child of the second husband.
- 3. These presumptions may be rebutted only through action to disclaim paternity."

Art. 63 of the Code of the Family and Guardianship:

"The husband of the mother may take action to disclaim paternity within six months of learning of the birth."

Art. 85 of the Code of the Family and Guardianship:

- "1. The man who had intercourse with the mother of the child between three-hundred days and one-hundred-and-eighty-one days before its birth shall be presumed to be its father.
- 2. The fact that, during that period, the mother also had intercourse with another man shall rebut this presumption only if, under the circumstances, the other man appears more likely to be the father."

Abuse of rights and public policy:

Art. 5 of the Civil Code:

"No person shall use their rights in a manner contrary to the social and economic purpose of those rights or the rules of life in society. Abuse or abusive non-use of a right shall not be considered as exercise of that right, or enjoy the protection of the law."

Art. 58 para. 2 of the Civil Code:

"Any legal act contrary to the rules of life in society shall be null and void."

Russian Federation

Under the Family Code (s.52 (3)), a spouse whose consent to artificial fertilization has been received in a form established by law shall not have the right to refer to these circumstances when contesting his paternity. Regarding surrogacy, there is a similar provision in the Family Code: both the spouses, who gave their consent to artificial fertilization and embryo implantation in a proper way, and a surrogate mother shall not have the right to refer to these circumstances when contesting their parentage after the entry of parents in the book of birth registrations has been made

Slovenia

In principle, no.

- Art. 41: Maternity cannot be contested if the mother had consented to the MAP procedure. When a donated egg is used, the donor cannot claim maternity for the child, nor can biological maternity be determined in the interest of other parties.
- Art. 42: Paternity may not be contested, unless it is claimed that the child had in fact not been conceived with a MAP procedure. In that case articles 96-99 of the Marriage and family relations Act apply.
 - When donated sperm is used, the donor cannot claim paternity for the child, nor can biological paternity be determined in the interest of other parties.

Sweden

Paternity is regulated in the Parental Code.

Paternity can be contested if, having regard to all the circumstances, it is not probable that the child was conceived by insemination or IVF.

Turkev

DNA tests.

United Kingdom

Whether patients' own gametes are used in assisted fertility treatment or whether donor gametes are used, where the couple is either married or in a civil partnership, both parents will be the legal parents of any child born from the treatment from the date of birth of the child. The law endeavours to put couples who have had assisted fertility treatment in a similar position to couples who conceive naturally as regards legal parenthood and parental responsibility. It is however possible for the father or second parent (in the case of a female same sex couple who are in a civil partnership) to resist legal parenthood but only where the person can demonstrate that he or she did not consent to their partner's treatment (see section 35(1) and section 42(1) of the HFE Act 2008).

When donor gametes are used in treatment, and where the couple having treatment is neither married nor in a civil partnership, the second parent (i.e. not the birth mother) can acquire legal parentage if the agreed parenthood conditions are met (see section 37 and 44 of the HFE Act 2008). In cases where the agreed parenthood conditions are not met, parenthood will be in question and in order to establish legal parenthood, the couple would need to seek a declaration of parenthood from Court.

Further information on legal parenthood can be found on these pages of the HFEA website: https://www.hfea.gov.uk/treatments/explore-all-treatments/becoming-the-legal-parents-of-vour-child/

Definitions of mother and father in accordance to (HFE) Act 2008 are as follows: Meaning of "mother"

(1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.

- (2) Subsection (1) does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.
- (3) Subsection (1) applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

Meaning of "father"

- 35 Women married at time of treatment
- (1) If -
 - (a) at the time of the placing in her of the embryo or of the sperm and eggs or of her artificial insemination, W was a party to a marriage, and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage, then, subject to section 38(2) to (4), the other party to the marriage is to be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her artificial insemination (as the case may be).
- (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)(a)

Canada

In Canada, issues of maternity and paternity are within the jurisdiction of the provinces and territories. Most of the provincial and territorial family law statutes contain a provision regarding declarations of parentage. These provisions allow for interested persons to apply to a court for a declaratory order that a female person is the mother of a child. Similarly, the various provincial and territorial statutes also allow for interested persons to apply to a court for a declaratory order that a male person is or is not recognized in law to be the father of a child.

Certain provincial and territorial family laws specifically refer to parentage as it relates to assisted human reproduction. For instance, the Civil Code in the province of Quebec has specific provisions that deal with the filiation of children born of assisted procreation. It clearly provides that there is no bond of filiation between the contributor of genetic material and the resulting child.

The legislation in Newfoundland and the Yukon specifically deal with parentage and artificial insemination. The legislation provides that a man who is married or cohabiting with a woman who is artificially inseminated, whether with the man's semen or not, is deemed to be the father of the resulting child if he consented in advance to the insemination. Further, the legislation also provides that a man whose semen was used to artificially inseminate a woman with whom he is not married or cohabiting at the time of the insemination is not in law the father of the resulting child.

The province of Alberta is in the process of updating and consolidating various provincial statutes dealing with family law matters. Parentage in the context of surrogacy and artificial insemination is included in the new legislation, which has yet to come into force.

Israel

No, because when a surrogate mother is involved, there is a specific law stating that there are no parenthood rights for the surrogate mother. In all other cases, the rule is that the woman who gives birth is the mother, subject to the adoption act.

<u>Section III – Current debate and specific situations met in your country, in relation to these issues</u>

19. Is there an important current debate in your country on these or related issues? If so, what might the implications be (e.g. changes to the legal situation)?

| Country | Reply | Country | Reply |
|---------------------------|-------|------------------------|-------|
| Albania | | Luxembourg | * |
| Armenia | | Malta** | * |
| Austria | No | Republic of Moldova | |
| Azerbaijan | - | Netherlands | No |
| Belgium | * | Norway | * |
| Bosnia and Herzegovina | Yes* | Poland | - |
| Bulgaria | | Portugal | No |
| Croatia | No | Romania | |
| Cyprus | * | Russian Federation | No* |
| Czech Republic** | Yes* | San Marino | |
| Denmark | * | Serbia | - |
| Estonia | No | Slovakia | - |
| Finland | Yes* | Slovenia | No* |
| France | * | Spain | * |
| Georgia | * | Sweden | * |
| Germany | No* | Switzerland | Yes* |
| Greece | ı | "FYROM" | * |
| Hungary | * | Turkey | * |
| Iceland | Yes* | Ukraine | * |
| Ireland* | Yes* | United Kingdom | * |
| Italy | - | Canada | * |
| Latvia | * | Israel | - |
| Lithuania | No* | | |

Belgium

The issue of surrogate mothers regularly crops up in Parliament. A number of proposals have been made, some of which deal only with surrogacy in the context of MAP.

Bosnia & Herzegovina

As stated above, the issue of MAP is very high on political and public agenda in B&H, however no specific legislation has been approved so far, explicitly due to the opposition of conservative parties and influence of church. The main debate and controversy are around granting the rights to MAP to single women, as well as the issues of heterologous procreation (sperm/oocyte donation).

<u>Cyprus</u>

The drafting of a law regulating MAP and IVF is currently under consideration. For this purpose a Steering Committee has been established by the Ministry of Health. The Committee is composed of representatives from Services and interested groups on MAP issues.

Czech Republic

The debate is steady and intense, considering single person and homosexual couples' by state guaranteed access to MAR, explicit legal regulation of surrogate motherhood, increasing the number of IVF cycles covered by HI, changes in the age for MAR access.

Denmark

The ongoing debate in the Danish Parliament might lead to changes in the legal situation for surrogacy, but it is not possible to predict anything.

Finland

Surrogacy-related issues are debated every now and then.

France

The main principles of the Law on bioethics of 1994 have been confirmed by the Law of 6 August 2004 and made consensus. The transfer of embryos post mortem was discussed in particular but was not authorised.

These issues are subject to ongoing debate within society (especially the access of single women or female couples to MAP and surrogacy) and are regularly reported upon by the media.

No legal changes are planned before the next revision of the bioethics law (2018).

Hungary

Updating of the national regulation is intended in the next future.

Georgia

Debates took place about the draft Law on Reproductive Health and Reproductive Rights among the representatives of various professionals, especially medical professionals, representatives of church and religious groups, representatives of Ministry of Health and Social Affairs, etc.

As the above draft Law is more specific than the Law on Health Care it will change existing legal situation (details are already specified throughout the questionnaire).

<u>Germany</u>

The Federal Ministry of Justice and Consumer Protection has set up a working group to examine whether Germany's law of descent, including issues related to MAP, should be reformed.

Greece

No process of revision is currently foreseen for this Law.

Iceland

As previously stated, a debate has been ongoing on the necessity of revising the law on artificial insemination, specifically with regards to issues pertaining to embryonic stem cell research.

Ireland

Legislation pertaining to assisted human reproduction (AHR) is currently being developed. The draft General Scheme of legislative provisions has been completed and submitted to the relevant parliamentary committee which published the report of its review in July 2019, making recommendations which include proposals related to both broad policy objectives and more technical amendments. Its recommendations are being considered during the ongoing process of drafting this the AHR Bill. Until the enactment of the Children and Family Relationships Act 2015, the provision on assisted human reproduction treatment was largely unregulated. There has been and will continue to be widespread stakeholder engagement and national debate on these sensitive and complex matters.

<u>Latvia</u>

There was a great discussion in Saeima about surrogate mother. A conclusion has not yet been reached.

<u>Lithuania</u>

The public debate on MAP in Lithuania started in 2002, when the first Draft Law on Artificial Insemination was registered in the Parliament. Several alternative draft laws were introduced since that time. A summary of the debate which took place in the end of 2010 can be found at the official periodical "The Lithuanian Parliamentary Mirror" http://www6.lrs.lt/kronikos/pdf/ghxv-hx4j-13lzF7155No_4_148.pdf.

An extensive public debate also took place before the adoption of the recent Law on Medically Assisted Procreation of the Republic of Lithuania. Two different versions of the law were extensively discussed and a more restrictive version was adopted by the Parliament in June 2016. However, the law got a veto from the President of the Republic of Lithuania. The President was approached by a number of NGOs, universities, physicians' and patients' organizations. This resulted in adoption of the current version of the Law on Medically Assisted Procreation of the Republic of Lithuania.

Luxembourg

Opinion issued by the National Ethics Commission.

General debate in Parliament expected.

Malta

There is a need for a debate on this subject in Malta. A conference on "Bioethics and the Family" is being considered for next year to raise awareness about the issues and the need for legislation. This conference is being planned by the Bioethics Consultative Committee and Family Commission.

Norway

Egg donation, MAP to single women and surrogacy is debated.

Russian Federation

There are currently no important/serious debates on MAP among general public, including on surrogacy. However, there is a draft-law that aims to withdraw from a surrogate her right to keep a child, thus allegedly making surrogacy exclusively based on a contract. It is hard to say now what the chances are that this law will be adopted.

Slovenia

Not at present. However, in 2001, an amended law on medically assisted procreation was passed, making, among other things, the MAP services freely accessible to single women without male partners and without a medical fertility problem, which under the previous law (2000) had not been possible. An opposition group in the Parliament called for a legislative referendum, triggering fervent public debate. The National Medical Ethics Committee (NMEC) and the National Health Council advised against arbitrary use of medicine for interventions with far reaching consequences, when, such as in this case, there is no valid medical indication. The NMEC quoted the Ad Hoc Committee of Experts on Progress in Biomedical Sciences (CAHBI)'s Report on human artificial procreation, 1989, which restricts the use of MAP procedures to heterosexual couples and to the situations with strict medical indications (infertility, failure of other methods of treatment, need to avoid transmission of a grave disease) as in fact contained in the previous law.

In the referendum, the voters rejected the new law with an overwhelming, nearly 3:1, majority. As a result, the law of 2000 described above remained in force.

Spain

The Spanish Surrogate Association is promoting the legalisation of this method as another Assisted Reproductive Technology.

Sweden

In the recent publication on the 24th February 2016 "Olika vägar till föräldraskap (SOU 2016:11)" a government inquiry had been issued to consider different ways to increase the possibilities for involuntarily childless people to become parents. One legal change to occur on April 1st is that single women can now receive MAP. The inquiry has proposed that one should no longer demand a genetic link between the child and one of the parents, which might mean that embryo donation will become possible. The inquiry also included considering whether to permit altruistic surrogacy, if any, in Sweden. The inquiry's conclusion was that commercial surrogacy should not be permitted, nor should altruistic surrogacy, and that

society should also counter that type of surrogacy. The final report has been submitted to a large number of stakeholders, organisations and authorities, for comments by the 23rd June 2016.

In a new government inquiry followed by a law proposal by the government on the 15th March 2018 "Modernare regler om assisterad befruktning och föräldraskap (proposition 2017/18:155)" which will enter into force on January 1st, 2019, the legislator has made embryo donation possible. A couple or a single female may donate fertilized eggs if they already have children of their own and if the egg is genetically linked to one of them (or to the single female). The children born from embryo donation shall have a right to enter their personal information into the special registry to be kept about the donation for 70 years, for any possible genetic siblings to be retrieved upon request.

Switzerland

June 5th,2016, popular vote on the revision of the RMA regarding the regulation of PGS/PGD (prohibited until now):

http://www.bag.admin.ch/themen/medizin/03878/16024/index.html?lang=fr

"FYROM"

Some debates have just started in many professional organisations - obstetricians/gynecologists.

Ukraine

It is necessary to renew Decree of the Ministry of Health.

United Kingdom

As referred to at 18 above, in cases where the agreed parenthood conditions of the HFE Act 2008 have not been met, legal parenthood does not automatically follow for the second parent. In such cases one of the only remedies for the second parent to seek a declaration of legal parenthood from the Court. See for example the recent case (Neutral Citation Number: [2015] EWHC 2602 (Fam) which can be found here: https://www.judiciary.gov.uk/wp-content/uploads/2015/09/parentage.pdf

<u>Turkey</u>

These issues are at present being discussed by the related circles (ie. Medical schools, Councils of Medical Doctors, Lawyers).

Canada

During the 1980s, scientific advances in the area of reproductive technologies and a growing awareness of the legal, ethical and social issues related to reproductive technologies prompted individuals and groups in Canada to pressure the federal government to examine the complex issues related to these technologies. In response to this pressure, the federal government appointed the Royal Commission on New Reproductive Technologies in October 1989. The mandate of the Royal Commission was quite broad. In addition to the task of examining the current and potential scientific and medical developments related to new reproductive technologies, it was also mandated to consider: (1) the impact of the technologies on society as a whole, (2) their impact on identified groups within society, such as women and children, and (3) the ethical, legal, social, economic and health implications of the new technologies.

After an extensive consultation process with citizens, the scientific and medical communities and the social science community, the Royal Commission released its final report in 1993, which included 293 recommendations.

After more than a decade of consultation, an Act respecting assisted human reproduction and related research became law on March 29, 2004. As outlined above, the coming into force of the provisions of the Act will follow a staged approach. The first set of provisions came into force on April 22, 2004. This set of provisions contained a number of prohibitions, including those related to commercial surrogacy and the purchase of sperm or ova from donors and most of the provisions on controlled activities, such as the manipulation of human reproductive material to create a human embryo.

During the legislative process and witness testimony before committees in both Houses of Parliament, it was evident that a number of different viewpoints or perspectives existed with respect to certain issues addressed in the Act. For example, some of the most compelling testimony before the Senate Committee was with respect to gamete donation. In particular

whether a non-anonymous donation scheme or an anonymous donation scheme should be adopted.

20. Delegations are invited to provide information, in this section, on particular cases encountered in their country, and especially their case-law, in relation to the questions appearing in Sections I and II above

Please provide relevant articles of the law concerning MAP (including family law), where possible translated in English or French.

Azerbaijan

The law on reproductive health is being elaborated. Many aspects of MAP were included during discussions on the draft law.

Belgium

Belgian case-law on surrogate mothers.

Brussels Youth Court (12th ch.) 6 May 2009, J.L.M.B. 2009, liv. 23, 1083:

According to the Civil Code, the mother who carried the child is the legal mother since she is the one who gave birth to him or her. In 1987, lawmakers proceeded from the biological assumption that the person giving birth was necessarily the mother of the child. Today, scientific advances require us to sometimes make a distinction between the genetic mother and the gestational mother. The adoption procedure is therefore used to fill a gap in the law or, at the very least, to deal with a situation that it failed to envisage.

Liège Court of Appeal (1st ch.) 6 September 2010, J.L.M.B., 2011, 2, 52:

The court found that a surrogacy agreement drawn up in casu in the United States between an American surrogate and two men of Belgian nationality was a violation of public policy, and that its unlawfulness contaminated the birth certificates drawn up on the basis of the contract. The unlawful nature of the contract must not jeopardise the best interests of the children, however.

Accordingly, recognition may be granted to the birth certificates in that they establish a paternal filial link with the biological father. They cannot be recognised, however, insofar as they mention a filial link with the biological father's companion, as there can be no dual paternity except in the case of adoption.

Croatia

There is no case-law on MAP subject.

Unfortunately translated into English is only draft of the act, which slightly differs from the adopted version. In the attachments are both: draft in English and Act in Croatian.





Proposal of the Zakon MPO.docx Medically Assisted Fe:

Cyprus

There is no case-law up-to-date.

<u>Finland</u>

Paternity Act (*isyyslaki*; 11/2015): unofficial English translation available at: http://www.finlex.fi/en/laki/kaannokset/2015/en20150011.pdf>.

Act on Assisted Fertility Treatments (*laki hedelmöityshoidosta*; 1237/2006) unofficial English translation available at:

http://www.finlex.fi/fi/laki/kaannokset/2006/en20061237.pdf NB: This translation does not include the latest updates.

Maternity Act (*äitiyslaki*; 253/2018): <u>unofficial English translation available at:</u> https://www.finlex.fi/en/laki/kaannokset/2018/20180253>

France

Public health code

Articles L. 1244-1 to L. 1244-9 Articles L. 2141-1 to L. 2142-4

Civil code

Article 16-7 Articles 311-19 and 311-20

Criminal code

Articles 511-6, 511-9 to 511-13 and 511-22 to 511-25-1

Hungary

In 2015 a case has been concluded by the Hungarian supreme court (Kúria) where paternity was contested after MAP based on the exception if the husband had not consented to the MAP intervention.

The married couple separated shortly after the birth of the child. The couple had agreed about procreating a child with MAP intervention. The separated husband contested his paternity because a genetic DNA test excluded his biological parentship while supported that of the mother. The court has accepted the action of the ex-husband not to be the father based on the fact that he consented to generate a child with MAP but did not consent to the actual intervention; the document of consent did not contain that the sperm might come from a foreign donor. Not the fact that he could not be the biological father but the lack of a legally valid declaration of consent served as the base of the judgement. (Case EBH2015 P.8.)

Georgia

English versions of the following legislation related to MAP are presented in the Addendum:

- a) Law on Health Care (Relevant articles from Chapter XXIII Family Planning) [see Addendum]:
- b) Draft Law on Reproductive Health and Reproductive Rights [see Addendum].

Germany

See section I above for links to the updated versions of German laws

Ireland

Roche -v- Roche & ors (2009)

Supreme Court unanimously dismissed an appeal by a separated mother requesting to have three frozen embryos implanted in her womb against the wishes of her estranged husband.

The appeal was brought on the following grounds:

- To decide whether there was a legally enforceable agreement between the parties as to what would happen to the frozen embryos
- To decide whether constitutional protection afforded to the life of the "unborn" (Article 40.3.3) extends to the 3 frozen embryos at issue.

Judgment

Legally Enforceable Agreement:

During their treatment the parties signed four consent forms as required by the clinic. As consent forms, they were found not to contain the necessary criteria for legal contracts. None of the consent forms dealt with the three surplus frozen embryos, therefore, there was

none of the consent forms dealt with the three surplus frozen embryos, therefore no evidence that the respondent gave his consent to their implantation.

Constitutional Protection:

Article 40.3.3 of the Irish Constitution protects the right to life of the unborn "with due regard to the equal right to life of the mother". The Court interpreted this provision as meaning there must be a physical link between the unborn and the mother i.e. implantation in the womb.

The Court decided that the purpose of the 8th Amendment to the Constitution (1983 Referendum) was to prevent the de-criminalisation of abortion and that issues relating to IVF were not considered or foreseen.

A number of the Judgments stated that if respect for an embryo were carried to the point of equating it to the "unborn" a situation might arise where some methods of contraception e.g. morning after pill would be outlawed.

High Court Ruling:

http://www.courts.ie/Judgments.nsf/bce24a8184816f1580256ef30048ca50/e5617d292b7b6b268025724800329992?OpenDocument

Supreme Court Ruling:

http://www.courts.ie/Judgments.nsf/0/0973CBD1FD5204028025768D003D60F7

MR and Anor – v- An tArd Chlaraitheoir & Ors [2014]

This case concerned an arrangement whereby a woman agreed to act as a surrogate for her sister and brother-in-law (the commissioning couple). The commissioning couple provided the genetic material (egg and sperm), which ultimately resulted in the birth of twins. The commissioning couple sought to have the birth register altered so that both the commissioning couple were registered as the legal parents. The Registrar refused to do so, on the principle that he woman who has given birth to a child is always regarded as the legal mother. That refusal was challenged in the High Court.

In his judgment of 5th March 2013, Justice Abbott found in favour of the commissioning couple. He held that the genetic mother, and not the birth mother, was the mother, and that the person with the genetic/blood link was entitled to be registered as the parent on the birth certificate.

In February 2014, the State appealed Justice Abbott's decision on the grounds that: it could create uncertainty regarding the parentage and parental rights of children born as a result of egg donation; demean the role of birth mother; lead to an opinion that commercial surrogacy is not unlawful; and result in the Registrar requiring genetic proof of maternity for every birth.

In November 2014 the Supreme Court overturned the High Court decision on the basis that the case had raised important, complex and social issues which are best addressed by the Oireachtas rather than the judiciary.

High Court Ruling:

http://www.courts.ie/Judgments.nsf/bce24a8184816f1580256ef30048ca50/e3f0dc917872554c80257b250052dab3?OpenDocument

Supreme Court Ruling:

http://www.courts.ie/Judgments.nsf/0/E238E39A6E756AB480257D890054DCB6

Children and Family Relationships Act 2015 – Parts 2 and 3 deals with parentage matters arising from donor assisted human reproduction. It is available at http://www.irishstatutebook.ie/eli/2015/act/9/enacted/en/html

<u>Italy</u>

- ART 1-4 Access to assisted reproductive technology is allowed only when the causes
 of sterility cannot be defeated by other means. The techniques are applied according
 to principle of graduality and with the written and informed consent of the couple.
- ART 5 Only heterosexual couples over the age of eighteen that are of potentially fertile age have access to ART.
- Art 8-9 The child born after ART has the status of legitimate and acknowledged child and it can not be disavowed.
- ART 10-11 ART can be performed only in authorized and accredited Centres by Istituto Superiore di Sanità.
- ART 13-14 Any experimentation on embryo is prohibited. Observational clinical research on embryos is permitted only in the interest of the embryo.
- More embryos than the number necessary for a single contemporary implantation are not allowed to be produced (The number required is no more than three).

- Crioconservation is allowed only if required by a particular (transitory) woman's health condition.
- ART 16. Conscientious objection is also recognized

Luxembourg

It is important to note that MAP is currently not regulated in Luxembourg, except that

- Article 312 of the Civil Code states that a paternity suit is non-admissible by the husband of the mother "if it is established, by all means of proof, that the child has been conceived by means of artificial insemination, either by the husband or by a third party with the written consent of the husband".
- the national hospital plan adopted in 2001 through regulation, envisages the creation of a service of MAP in a general hospital containing an obstetrics department.

In the meantime, the creation of a MAP department has effectively been authorised to the Hospital Centre of Luxembourg. This department is in place. The data supplied to the questionnaire reflects the practices of this department.

There exists a legal proposal, of which a bill is before parliament, with regard to MAP. Parliament had anticipated holding a large debate but as yet this debate has not yet taken place.

The National Ethics Commission has produced a very complete opinion on all aspects of MAP

Malta

- There are doubts as to whether all medically assisted procreation in Malta use husband's sperm;
- There are concerns that men are being offered sums of money to donate sperm;
- There is evidence that the number of ova being taken from a woman's ovary was higher than the amount which both scientifically and ethically makes sense. This can endanger the health of women (hyper stimulation syndrome).
- There is concern that more than two or three embryos are being transferred into a woman's uterus.
- There are concerns about the current services being provided to infertile couples. These include: the need for infertile couples to be managed with more sensitivity; and the need for the couple to be given information and counselling about treatment options and associated risks, about possible solutions and their likelihood of success and failure.

Poland

Homologous insemination in a married couple has no legal incidence: the mother's spouse becomes the child's biological father; the means of conception (natural or artificial) has no legal incidence, nor does consent or the lack of it.

Heterologous insemination, on the other hand, raises legal questions concerning filiation. The donor of the sperm is certainly the child's biological father, but it is impossible to prove legal paternity as the identity of the donor is in principle unknown to the mother and the doctor is sworn to secrecy. Furthermore, no action to prove paternity may be opened in this case as Article 85 para. 1 of the Code of the Family and Guardianship makes sexual intercourse a prerequisite of such action.

The question of the legal paternity of the child thus remains open. In the case of an unmarried woman, action to prove paternity should be excluded, as the donor has the right to remain anonymous. However, if the child is born in wedlock or within 300 days of the marriage being dissolved or annulled, the mother's husband is presumed to be the legal father. He may take action to contest his paternity within six months of finding out about the birth (art. 63). This is a peremptory time limit, after which only the public prosecutor may institute such proceedings.

The situation is more complex in the event of heterologous insemination carried out with the husband's consent. As there are no specific legal provisions in the matter, the husband has the right to contest his paternity even though he did give his consent. Theoretically he only needs to prove that the birth was the result of MAP. However, according to a decision of the Court of Cassation on 27 October 1983: "Action by the spouse of the mother contesting paternity of a child born following MAP performed, with said spouse's consent, with the sperm

of another man may be considered contrary to public policy." In stating its reasons, the Court stressed the importance of the child's welfare, arguing that if it were to accept an action contesting the father's paternity of a child born following MAP carried out with his consent using another man's sperm, the child would, to all intents and purposes, be fatherless; it would be virtually impossible to prove the paternity of the donor because of the rules protecting his anonymity. And the donor has no interest in proving his paternity. This interpretation also takes into account the interests of the family formed subsequent to the couple's decision to have recourse to MAP.

Russian Federation

Regarding the cases please see the Doc DH-BIO(2016)4 Addendum (replies to Q. 3)

Articles:

Research Journal of Applied Sciences 10 (12): 841-844, 2015;

Khazova O., Chapter 19. Russia / (eds.) K. Trimmings and P. Beaumont, 'International Surrogacy Arrangements. Legal Regulation at the International Level'. Studies in Private International Law. Oxford: Hart Publishing, 2013;

Borisova T.E., Surrogate Motherhood in Russian Federation: Problems of Theory and Practice. Moscow, 2012 (in Russian);

Vershinina E.V., Kabatova E.V., Yashmetova M.O. Surrogate Motherhood in Russian and Foreign Countries: Comparative-Legal Analysis // (2011) *Family and Housing Law* No. 1 (*in Russian*).

Romanovsky G.B., Legal Regulation of Assisted Reproductive Technologies (Surrogate Motherhood as an Example). Moscow, 2011 (in Russian);

Kolokolov G.R., Legal Foundations of Medical Interference in Human Reproductive Activity (Artificial Insemination) // (2005) 2 *Russian Law: Theory and Practice* 210;

Khazova O. Legal Aspects of Application of Assisted Reproduction Methods in Russia / (ed.) O. Dubovik, 'Problems of Medical Law'. Moscow. 2003 (*in Russian*);

Khazova O., Genetics and Artificial Procreation in Russia – in: <u>'Biomedicine, the Family and Human Rights'</u> /Ed. by M.-T. Meulders-Klein, R. Deech, and P. Vlaadingebroek. Kluwer Law International, The Hague, 2002. Pp.377-391.

<u>Slove</u>nia

The matter of the law is published in:

ZUPANCIC, Karel, MEDEN-VRTOVEC, Helena, TOMAZEVIC, Tomaz, ZNIDARSIC, Viktorija. The future law on infertility treatment and on biomedically assisted procreation in Slovenia. J. assist. reprod. genet., Oct. 2000, vol. 17, issue 9, pp. 496-497.

(The paper refers to the draft, but the final version is essentially unchanged).

Information on some other aspects of the legislation and practice of MAP in Slovenia are contained in a IFFS survey (See Addendum).

United Kingdom

R (TT) v Registrar General for England and Wales & Ors ((2019) EWHC 2384 (Fam))

The case concerns a transgender man (TT) who has a gender recognition certificate (GRC) confirming that he is male for all legal purposes except the limited exceptions set out in the Gender Recognition Act 2004 (GRA). TT had artificial insemination using donor sperm in a licenced fertility clinic, fell pregnant as a result, gave birth to a child, in 2017. He tried to register the birth as the father but was refused by the Registrar General (RG) who was only able to register the birth with TT as the mother. The birth has remained unregistered.

The judgement was handed down on 25 September 2019. The judge supported the Government's position that a person who gives birth to a child (i.e. including a trans man such as TT) will be the child's mother. The Government's view is that the judgment has no effect on the availability of regulated fertility treatment in the UK. The Government considers that regulated fertility treatment is currently, and will remain, equally available to all (trans) women and (trans) men under the Human Fertilisation and Embryology Acts.

"FYROM"

Current healthcare law predates the era of MAP. No updates concerning MAP have been made

In family law there are standard articles addressing the contesting of the paternity but not in relation to MAP.

Canada

Examples of Provisions Respecting Parentage in Provincial and Territorial Legislation

- Alberta Domestic Relations Act, R.S.A. 1980, c. D-37
- Ontario Children's Law Reform Act, R.S.O. 1990, c. C-12
- Newfoundland Children's Law Act, R.S.N. 1990, c. C-13
- Provincial and Territorial Family Law Provisions that Specifically Address Parentage and Artificial Insemination:
- Newfoundland Children's Law Act, R.S.N. 1990, c. c-13
- Yukon Children's Act, R.S.Y. 1986, c.22
- Quebec Civil Code of Quebec
- STATUTES OF CANADA 2004, CHAPTER 2 An Act respecting assisted human reproduction and related research, BILL C-6 ASSENTED TO 29th MARCH, 2004
- Alberta Court of Queen's Bench Judicial District of Calgary
 IN THE MATTER OF The Child Welfare Act AND IN THE MATTER OF the Application of
 "A" for an adoption order in respect of the child "C" born on the 30th day of October,
 1994.
 - AND IN THE MATTER OF the Application of "K" for an adoption order in respect of the child "M" born on the 9th day of April, 1987., and Psychologists Association of Alberta, intervener
- Nova Scotia Supreme Court (Family Division) Nova Scotia (Birth Registration No. 1999-02-004200)(Re) IN THE APPLICATION OF S.C.M. and N.J.C. to adopt the person whose birth is registered as Registration No. 1999-02-004200 by the Registrar General for the Province of Nova Scotia under The Children and Family Services Act, being Chapter 5 of the Statutes of Nova Scotia, 1990 AND IN THE APPLICATION OF S.C.M. and N.J.C. to adopt the person whose birth is registered as Registration No. 94-02-006955 by the Registrar General for the Province of Nova Scotia under The Children and Family Services Act, being Chapter 5 of the Statutes of Nova Scotia, 1990.
- Food and Drugs Act Processing and Distribution of Semen for Assisted Conception Regulations.

APPENDIX I

Surrogate mothers

12. Is surrogacy permitted in your country? If yes, describe all conditions regulated by law

| Country | Reply | Country | Reply |
|-------------------------|-------|--------------------------|-------|
| Albania | | Lithuania** | No* |
| Andorra | No | | |
| Armenia | | Luxembourg | * |
| Austria | No | Malta | * |
| Azerbaijan | No | Republic of Moldova | |
| Belgium | Yes* | Netherlands* | Yes* |
| Bosnia & Herzegovina | | Norway | No |
| Bulgaria | | Poland | No* |
| Croatia | No | Portugal | No |
| Cyprus | * | Romania | |
| Czech Republic | No | Russian Federation | Yes* |
| Denmark | Yes* | Serbia and Montenegro | No* |
| Estonia | Yes | Slovakia | No |
| Finland | No* | Slovenia | No |
| France | No | Spain | No |
| Georgia | Yes* | Sweden | No |
| Germany | No | Switzerland | No |
| Greece | Yes* | "FYROM" | No* |
| Hungary | | Turkey | No |
| Iceland | No | Ukraine | Yes* |
| Ireland | | United Kingdom | Yes* |
| Italy | No | Canada | Yes* |
| Latvia | * | Israel | Yes* |

Belgium

In the absence of specific legislation concerning surrogate mothers, surrogacy is not prohibited. According to the Belgian Civil Code, the woman who gives birth to the child is the legal mother but the filial relationship may be severed by full adoption.

If, however, an agreement is concluded between the parties, it will have no legal value owing to the principle of non-disposability of the human body and the principle of non-disposability of personal status.

Cyprus

There is no legal provision referring to surrogate mothers.

Denmark

Surrogacy is a part of the legislation concerning adoption. It is forbidden to give or receive help in order to make a match between a surrogate mother and a woman wanting a child. Arrangements concerning custody or granting adoption are forbidden, if there is money involved in the transaction. If there exists an agreement between two women on surrogacy, MAP is forbidden. Such agreement between two women is invalid and a surrogate mother is

not bound to give the child to the other party and the woman in question is not bound to receive the child.

Finland

According to the Act on Fertility Treatments (*laki hedelmöityshoidoista*; 1237/2006), MAP cannot be provided if it is evident that the future child will be adopted. Prior to the entry into force of the provision in 2007, there had been about 20 surrogate pregnancies in Finland.

Georgia

Both, the Law on Health Care and draft Law on Reproductive Health and Reproductive Rights permit surrogacy.

LHC:

Surrogacy is allowed for a couple if the woman has no uterus. The written consent of the couple is mandatory. If a child is born, the "surrogate mother" has no right to be considered as a mother. Couple is considered to be parents with all related responsibilities and rights.

There are no other specific provisions in the Law on Health Care about surrogacy.

DL-RHRR:

The draft Law defines surrogacy as "an agreement between an infertile couple and a woman, whereby the woman agrees to pregnancy by means of assisted reproductive technologies and delivers the child to the couple after birth."

The draft Law sets out the following principles for surrogacy:

- a) The right to apply for surrogacy is granted only to an infertile couple married under the rules established by legislation of Georgia. Surrogacy is not accessible for single women.
- b) Surrogacy is allowed only for altruistic purposes.
- c) Only gestational surrogacy is permitted (i.e. when embryo is created as a result of in vitro fusion of donors'/donor' and/or infertile couple's gametes); Ovum of surrogate mother shall not be used for creation of embryo.
- d) It is prohibited to engage in surrogate motherhood for financial gain.
- e) It is prohibited to force somebody to become a surrogate mother.
- f) Medical personal are obligated not to participate in the process of surrogacy, if there is a reason to assume that the surrogacy will be carried out for obtaining financial gain.
- g) A surrogate mother must be a legally competent woman of reproductive age, who has given birth to at least one live child.
- h) A married woman can become a surrogate mother only with the written, informed consent of her husband.
- i) The list of medical criteria, which must be met by a surrogate mother, as well as the list of obligatory medical tests, that a surrogate mother must undergo, is determined by the legal act of the Minister.
- A surrogate mother has no right to be recognized as a parent of a child born as a result of surrogacy.
- k) Only the childless couple are considered to be the parents of a surrogate child.

Greece

Conditions regulated by law:

- a. petition to the Court is required by the woman who desires a child under the condition that she is medically unable to deliver a child and the surrogate mother is healthy.
- b. a written and without any compensation agreement between the persons who want to have a child, the surrogate mother and, in case she is married, her husband
- c. approval by the Court.

Latvia

It is not mentioned in law.

Lithuania**

Surrogacy is prohibited by the Law on Medically Assisted Procreation (Art. 11) in Lithuania.

Luxembourg

Currently no legislation.

Malta

There is no legal framework.

Netherlands

Although surrogacy by in vitro fertilization is allowed, the policy attitude has been one of reserve. Lately this has changed, resulting e.g. in the recent starting of a second clinic offering surrogacy for same sex couples. The penal code currently contains some prohibitions, especially with regard to commercial surrogacy. A new act is in preparation to regulate surrogacy. It is expected to be sent to parliament for approval after the summer of 2020.

Poland

There are no specific legal provisions on the subject. Surrogacy contracts are considered contrary to the general rules of law: the free formation of kinship ties is not permitted, and parental authority may not be transmitted by civil law contract. Such a contract would also be contrary to the spirit of Polish law on families and descent, and to the rules governing life in society. The Polish Association of Obstetricians considers the use of surrogate mothers contrary to medical ethics because of the risk of conflict between the genetic mother and the mother who gives birth to the child.

Russian Federation

Russian law expressly permits the so-called full, or "gestational" surrogacy. The Family Code s.51 (4 (2)) states: "Persons who are married to each other and who gave their consent to the implantation of an embryo in another woman for the purpose of bearing may be entered as the child's parents only with the consent of the woman who gave birth to the child (surrogate mother)".

Russian law proceeds from the fact a woman who gave birth to a child is the child's mother, and that the surrogate has the right to decide whether to keep the child or not. It follows from the above-mentioned Family Code provision about the surrogate mother's consent.

To become a surrogate mother a woman, apart from being mentally and somatically healthy, must be of 20 - 35 years of age and must have her own healthy child.

Russian law does not contain any provisions on partial, or "traditional" surrogacy (what is, in fact, artificial insemination with donor's sperm). If partial surrogacy had been performed, it would be most probably recognized illegal.

Serbia and Montenegro

Surrogacy is not provided in the future draft law.

"FYROM"

No legal regulations.

Ukraine

Family Code of Ukraine dtd 1 January 2004 (see Section I).

United Kingdom

Surrogacy arrangements, including advertising for surrogates and payments to them, are regulated by the Surrogacy Arrangements Act 1985. The criteria for obtaining a parental order, which transfers legal parentage from the surrogate and her partner to the commissioning couple, is included in The Parental Orders (Human Fertilisation & Embryology) Regulations 1994, made under the HFE Act.

Canada

Pursuant to the Act, commercial surrogacy arrangements are prohibited. Section 6 of the Act prohibits a person to pay, offer to pay, or advertise to pay a woman to become a surrogate mother. The Act also prohibits a person to accept consideration for arranging, offering or advertising to arrange, the services of a surrogate mother. Further, it is prohibited for a person to pay, offer to pay, or advertise to pay consideration to another person to arrange for the services of a surrogate mother. Finally, the Act prohibits a person to counsel or induce a female person under the age of 21 to become a surrogate mother or undertake an AHR procedure to assist her to become a surrogate mother. The rationale behind the prohibition on commercial surrogacy is that allowing commercial surrogacy arrangements might lead to

the inducement of women to enter into a surrogacy agreement purely for financial gain. However, the legislation will not prohibit altruistic surrogacy arrangements.

Israel

Available for heterosexual couples only.

13. If yes, can the surrogate mother be legally remunerated?

| Country | Reply | Country | Reply |
|-------------------------|-------|--------------------------|-------|
| Albania | | Lithuania | - |
| Andorra | | | |
| Armenia | | Luxembourg | - |
| Austria | - | Malta** | - |
| Azerbaijan | - | Republic of Moldova | |
| Belgium | No | Netherlands* | No* |
| Bosnia & Herzegovina | | Norway | - |
| Bulgaria | | Poland | No* |
| Croatia | ı | Portugal | - |
| Cyprus | ı | Romania | |
| Czech Republic | - | Russian Federation | * |
| Denmark | No | Serbia and Montenegro | - |
| Estonia | - | Slovakia | - |
| Finland | - | Slovenia | _* |
| France | - | Spain | No |
| Georgia | * | Sweden | - |
| Germany | - | Switzerland | - |
| Greece | No* | "FYROM" | - |
| Hungary | | Turkey | - |
| Iceland | - | Ukraine | No* |
| Ireland | | United Kingdom | Yes* |
| Italy | No | Canada | Yes* |
| Latvia | - | Israel | Yes |

Georgia

LHC: no specific provisions are included in the LHC on remuneration.

DL-RHRR: No

However draft Law obligates an infertile couple to cover expenses related to:

- a) Medically assisted reproductive technology(ies), including medical tests for the surrogate mother, according to the rules established by this law;
- b) The surrogate mother's pregnancy, labour, and post-labour medical services, and newborn child's care and treatment;
- c) Legal and other related issues necessary for drawing up a surrogacy contract;
- d) Any other expenses related to surrogacy, including the loss of possible income, as long as the compensation doesn't imply a financial benefit for the surrogate mother.

Greece

According to Art 13, para 4 of Law 3305/05 the surrogacy agreement does not include any remuneration. Expenses related to pregnancy, delivery or confinement and compensation for

absence from work are not considered to be remuneration. The National Authority of MAP decides on the level of compensation.

Netherlands

Cost can be remunerated. Which costs may be remunerated is currently under debate. Commercialization of surrogacy is not allowed.

Poland

Such a contract would be considered unlawful and immoral.

Russian Federation

Most probably, the answer should be "Yes", because there are no provisions in law that forbid remuneration.

Slovenia

Art. 7: both paid and unpaid surrogate motherhood is excluded.

Ukraine

It is possible that she is remunerated by the couple.

United Kingdom

The surrogate can only receive payment of reasonable expenses. This is also a criteria for obtaining a parental order. No other money can be paid unless authorised by a court.

Canada

A surrogate mother cannot financially gain, but once in force, section 12 of the Act will allow for the reimbursement of receipted expenditures incurred in relation to the surrogacy, including compensating the surrogate for loss of work-related income during the pregnancy if continuing to work may pose a risk to her health or to that of the developing foetus.

14. If surrogacy is forbidden in principle, are there exceptions?

| Country | Reply | Country | Reply |
|-------------------------|-------|--------------------------|-------|
| Albania | | Lithuania | No |
| Andorra | Yes* | | |
| Armenia | | Luxembourg | - |
| Austria | No | Malta | - |
| Azerbaijan | No | Republic of Moldova | |
| Belgium | - | Netherlands | - |
| Bosnia & Herzegovina | | Norway | No |
| Bulgaria | | Poland | No |
| Croatia | No | Portugal | No |
| Cyprus | - | Romania | |
| Czech Republic | No | Russian Federation | - |
| Denmark | - | Serbia and Montenegro | No |
| Estonia | - | Slovakia | No |
| Finland | No | Slovenia | No |
| France | - | Spain | No |
| Georgia | - | Sweden | No* |
| Germany | No | Switzerland | No |
| Greece | - | "FYROM" | No |
| Hungary | | Turkey | No |
| Iceland | No | Ukraine | - |
| Ireland | | United Kingdom | - |
| Italy | No | Canada | - |
| Latvia | * | Israel | - |

<u>Andorra</u>

In case of requests for registration of foreign titles proving a familial relationship, but there must exist a biological relationship with at least one of the applications, all in the best interests of the child. (Article 12.4 of the Act)

Latvia

If it is not mentioned in law, it is practically possible to do.

Sweden

No, but if the surrogacy has been done abroad it has to date not been criminalized.

15. Are you aware of illegal practices in your country?

| Country | Reply | Country | Reply |
|-------------------------|-------|--------------------------|-------|
| Albania | | Lithuania | No |
| Andorra | No | | |
| Armenia | | Luxembourg | No |
| Austria | No | Malta | - |
| Azerbaijan | Yes | Republic of Moldova | |
| Belgium | No | Netherlands | No |
| Bosnia & Herzegovina | | Norway | No |
| Bulgaria | | Poland | No* |
| Croatia | No | Portugal | No |
| Cyprus | * | Romania | |
| Czech Republic | No* | Russian Federation | * |
| Denmark | No | Serbia and Montenegro | No* |
| Estonia | No | Slovakia | No |
| Finland | No* | Slovenia | No |
| France | No* | Spain | No |
| Georgia | No | Sweden | No |
| Germany | No | Switzerland | No |
| Greece | No* | "FYROM" | No |
| Hungary | | Turkey | No |
| Iceland | No | Ukraine | No |
| Ireland | | United Kingdom | No |
| Italy | Yes* | Canada | No |
| Latvia | - | Israel | No |

<u>Cyprus</u>

Since there is no law covering all of the above issues (12, 13, 14, 15), all the questions are not applicable.

Czech Republic

IVF is conducted only in selected centers of assisted reproduction in the Czech Republic. These are supervised on a regular basis

Finland

Couples are known to have used this practice abroad, in Russia, India or Pakistan. This is not illegal, but in many ways risky.

France

Aware of cases where French citizens used this practice abroad.

Greece

There has not been a known case.

Italy

There has been no indicted violation so far.

Norway

No - no such procedures are carried out in Norway.

Poland

Lack of data

Russian Federation

As have been stated before, Russian law does permit partial or traditional surrogacy. However, such cases are known to take place in practice.

Serbia and Montenegro

It would not be possible to establish a health institution providing MAP without the authorisation of Ministry of Health and registration for this activity.

Sweden

No, however it is becoming increasingly "normalized" / "accepted" in society by reports of Swedish citizens adopting children conceived by surrogacy abroad.