

I assent.

(L.S.)

**MARIE-LOUISE
COLEIRO PRECA
President**

21st June, 2018

ACT No. XXIV of 2018

AN ACT to amend the Embryo Protection Act, Cap. 524.

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same, as follows:-

1. (1) The short title of this Act is the Embryo Protection (Amendment) Act, 2018, and this Act shall be read and construed as one with the Embryo Protection Act, hereinafter referred to as "the principal Act".

Short title and
commencement.
Cap. 524.

(2) This Act shall come into force on such date as the Minister responsible for health may by notice in the Gazette appoint, and different dates may be so appointed for different provisions or different purposes of this Act.

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Amendment of
article 2 of the
principal Act.**2.** Article 2 of the principal Act shall be amended as follows:

(a) immediately after the definition "Directive", there shall be added the following new definition:

" "donor" means a third party who donates germ line cells to be used in medically assisted procreation:

Provided that donations by an ascendant to a descendant; descendant to an ascendant; siblings whether of the full or half-blood; persons related by affinity in the direct line shall not be permissible;"

(b) immediately after the definition "embryo" there shall be added the following new definitions:

" "embryo adoption" means that process established in this Act whereby embryos that are not transferred are gratuitously donated to the prospective parent or prospective parents:

Provided that this term does not have the same meaning and shall not produce the same effects of "adoption" under the Civil Code and the term "adoptive" shall be construed accordingly;

"embryo donation" means the transfer of an embryo resulting from gametes (spermatozoa and oocytes) that did not originate from the prospective parent or prospective parents;"

(c) the definition of "medically assisted procreation" shall be substituted by the following new definition:

" "medically assisted procreation" means all treatments or procedures that include the in vitro handling of human oocytes, spermatozoa or embryos for establishing a pregnancy. This includes, but is not limited to, intra-uterine insemination, in vitro fertilisation, intracytoplasmic sperm injection, embryo transfer, gamete, germinal tissue and embryo cryo-preservation, oocyte and embryo donation;"

(d) the definition of "prospective parent" shall be substituted by the following new definition:

" "prospective parent" means any person regardless of gender or sexual orientation, who has attained the age of

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majority and is a receiver or user of the medically assisted procreation techniques regulated under this Act;"; and

(e) immediately after the definition "prospective parent" there shall be added the following new definitions:

" "Protocol" means the protocol established in writing by the Authority in terms of this Act;

"tissue establishment" means a facility or a unit of a hospital or another body where the activities of processing, preservation, storage or distribution of human tissues and cells for human application are undertaken and it may also be responsible for procurement and, or testing of tissues and cells."

3. Article 4 of the principal Act shall be amended as follows:

Amendment of
article 4 of the
principal Act.

(a) in sub-article (1) thereof:

(i) in paragraph (a), for the words "medically assisted procreation;" there shall be substituted the words "medically assisted procreation and gamete donation;";

(ii) in paragraph (c), for the words "article 18 is" there shall be substituted the words "this Act are";

(iii) paragraph (f) shall be renumbered as paragraph (h) and immediately after paragraph (e) thereof, there shall be added the following new paragraphs:

"(f) to determine the eligibility and suitability or otherwise of a prospective adoptive parent in terms of the Protocol in those cases where it may give for adoption the embryos in terms of this Act and keep a register thereof;

(g) to keep a register of every medically assisted procreation procedure, germ line cell donation, cryo-preservation of germ line cells, cryo-preservation of embryos and embryo donation and adoption in terms of this Act which shall in all cases remain confidential;";

(b) sub-article (2) thereof shall be substituted by the following:

"(2) Notwithstanding the provisions of any other law and notwithstanding the provisions of article 7 but subject to the provisions of article 18, the Authority may give for adoption the embryos to a third party who qualifies for medically assisted

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procreation procedures, in those cases where:

(a) after the fertilization of the egg cells but before the implantation of the embryos into the womb has taken place death of the woman ensues; or

(b) for any other reason the implantation of the embryos into the womb of the prospective parent cannot take place including those cases where the prospective parent refuses said implantation or has reached the maximum permissible age for the implantation thereof or fails to renew the contract with the licensee where the cryo-preserved embryos are being stored for future use:

Provided that the Authority shall give for adoption the embryos when the prospective parent has reached the maximum permissible age for the implantation thereof.";

(c) sub-article (3) thereof shall be renumbered as sub-article (4) and immediately after sub-article (2), there shall be added the following new sub-article:

"(3) The adoption of an embryo may only take place if the Authority, on the application of a prospective parent or prospective parents, so decides:

Cap. 495. Provided that the Authority shall only issue its authorisation if the prospective parent or prospective parents have been declared as physically fit by a medical practitioner for the transfer of an embryo and following a favourable recommendation issued by the Adoption Board in accordance with the Adoption Administration Act determining the eligibility and suitability or otherwise of the prospective parent or prospective parents:

Provided further that the Authority shall make all reasonable efforts to match prospective adoptive parents with the embryos who require an adoption placement:

Provided further that, without prejudice to the provisions of sub-article (4) of article 9, the identity of the adopter or adopters and the persons from whom the germ line cells originated shall in all cases remain anonymous and the prospective parents shall only be entitled to such generic information as specified in the Protocol:

Provided further that the simultaneous implantation of embryos originating from different persons in a prospective parent during the same cycle is prohibited.";

(d) in the first proviso to sub-article (4) thereof as re-numbered:

(i) immediately after the words "Provided that" there shall be added the words "in the exceptional case when the embryo has not yet been adopted by the prospective parent or prospective parents";

(ii) for the words "into the womb" there shall be substituted the words "into the womb of the prospective parent"; and

(iii) the second proviso shall be substituted by the following:

"Provided that any person having a juridical interest, or in their absence their legal heir, within twenty days from the date of decision of the Authority for giving for adoption the embryos may file a sworn application in the Civil Court (Family Section) to enquire into the validity of the decision of the Authority and there shall be a right of appeal therefrom to the Civil Court (Family Section) before the Court of Appeal by means of an application filed within twenty days from the date of the decision of the Civil Court (Family Section). Where no application is filed before the Civil Court (Family Section) according to the provisions of this article, or where the judicial proceedings are withdrawn or discontinued, or where the judicial proceedings become *res judicata*, the decision of the Authority or the court becomes final:

Provided further that the embryo shall remain cryo-preserved until the decision of the Authority or the court becomes final."; and

(iv) immediately after sub-article (4) thereof as renumbered there shall be added the following new sub-articles:

"(5) When the decision of the Authority or the court giving an embryo for adoption becomes final,

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that embryo shall be considered as the embryo of the adopter or adopters and the persons from whom the embryo originated shall lose all rights and shall be freed from all obligations with respect thereto.

(6) Save as otherwise provided in this article, once the decision of the Authority giving an embryo for adoption becomes final, it shall be irrevocable."

Amendment of
article 6 of the
principal Act.

4. Article 6 of the principal Act shall be amended as follows:

(a) in paragraph (a) thereof, for the words "woman from whom the cell originated;" there shall be substituted the words "prospective parent;"

(b) paragraph (b) thereof shall be substituted by the following:

"(b) intentionally fertilizes more than five egg cells from one woman in one cycle of treatment:

Provided that the medical practitioner in charge of the medically assisted procreation may, in consultation with the multidisciplinary team and with the permission of the Authority, decide to fertilize more than two egg cells and up to a maximum of five fertilized egg cells within one treatment cycle provided that this is done in accordance with the Protocol established in writing by the Authority. Such Protocol shall be discussed in the Parliamentary Committee for Health within four weeks from date of publication:

Provided further that no more egg cells can be fertilized until all the cryo-preserved embryos have been implanted in the prospective parent from any prior medically assisted procreation treatments:

Provided further that where the prospective parent or prospective parents undergoing medically assisted procreation procedures do not expressly give their consent to the cryo-preservation of embryos and to the donation of fertilized eggs if necessary, in terms of article 18, it shall not be lawful to fertilize more than two (2) eggs within each treatment cycle.";

(c) paragraph (c) thereof shall be substituted by the following:

"(c) transfers more than two embryos into the prospective parent within each treatment cycle"; and

(d) paragraph (i) of the proviso thereof shall be substituted by the following:

"(i) the prospective parent in respect of the conduct referred to in paragraphs (a) and (d); and, or".

5. Article 7 of the principal Act shall be substituted by the following:

Substitution of article 7 of the principal Act.

"Cryo-preservation of germ line cells and embryos.

7. (1) Sperm cells may be cryo-preserved in authorized tissue establishments during the lifetime of the person from whom they originate.

(2) Oocytes may be cryo-preserved in authorized tissue establishments up to the maximum permissible age for the fertilization and transfer thereof into the prospective parent unless they are donated in terms of this Act:

Provided that, in any case, it shall not be lawful to extract and commence cryo-preservation of oocytes after the death of the person from whom they originate.

(3) Embryos which cannot be transferred into the prospective parent within a treatment cycle shall be cryo-preserved in licensed tissue establishments for future use by that prospective parent:

Provided that the cryo-preservation of embryos shall be regulated by an agreement between the prospective parent or prospective parents and the licensee subject to the prior authorisation of the Authority and shall have a maximum term of validity of five years renewable up to a maximum permissible age for the transfer thereof into the prospective parent in terms of the Protocol:

Provided further that when the maximum permissible age for the transfer of the embryo into the prospective parent is reached, the Authority shall authorize the donation of the cryo-preserved embryo.

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(4) Subject to the foregoing sub-articles, all other forms of preservation, of germ line cells and embryos are prohibited and whosoever contravenes this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment:

Provided that when there has been a breach of any provision of this Act, the Authority may order the cryo-preservation of any embryo.

(5) A prospective parent or prospective parents, who prior to the coming into force of this Act, have cryo-preserved embryos in tissue establishments abroad may apply to be granted an authorisation by the Authority to bring two cryo-preserved embryos to be transferred locally into the prospective parent or prospective parents for each cycle:

Provided that the Authority shall not authorise the transfer of more than two embryos for each cycle."

Amendment of
article 8 of the
principal Act.

6. Article 8 of the principal Act shall be amended as follows:

(a) sub-article (1) thereof shall be substituted by the following:

"(1) Whosoever, other than for the purpose of implantation in a prospective parent as may be authorized by the provisions of this Act, disposes of, hands over or acquires a human embryo produced outside the body, or removes such embryo from a prospective parent before the completion of implantation in the womb, shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment."; and

(b) in sub-article (2) thereof, for the word "embryo" there shall be substituted the words "fertilised egg".

Substitution of
article 9 of the
principal Act.

7. Article 9 of the principal Act shall be substituted by the

following:

"Donation and use
of germ line cells.

9. (1) The donation of germ line cells for the purpose of medically assisted procreation shall be a confidential agreement between the donor and the licensee:

Provided that prior to entering into such an agreement, the licensee shall duly inform the donor of the consequences thereof in terms of this Act:

Provided further that there shall be no link of filiation in accordance with the provisions of the Civil Code between the embryo fertilised using donated germ line cells and the donor.

(2) A donor must be over eighteen (18) years of age, have the legal capacity to contract and of good mental and physical health and further satisfies the criteria specified in the Protocol.

(3) A donor must not have attained the age of thirty-six (36):

Provided that the Authority may authorise a donor above this age limit in exceptional circumstances specified in the Protocol.

(4) Except in cases of a direct donation, the prospective parents or prospective parent shall only be entitled to obtain such generic information as specified in the Protocol about the donor whose identity shall in all cases remain confidential:

Provided that the medical records that may affect the health of the child and the identity of the donor or of the person from whom an adopted embryo originated shall be accessible to the child conceived from the germ line cells of such donor either upon the child reaching eighteen years of age or, subject to the consent of the Authority, at any earlier stage in exceptional circumstances in which the life or health of the child born from such germ line cells is at risk:

Provided further that the Authority shall keep the records of the identity of the donor for a period of hundred and ten years:

Provided further that if the Authority becomes aware of serious illness it shall be obliged to disclose the information to the parent or parents and, in the case that the child has attained majority, to the child.

(5) The donation of germ line cells for the purpose of medically assisted procreation shall be limited to one donation only and such donation shall be used in one prospective parent only.

(6) It shall be the responsibility of every licensee receiving donor germ line cells to verify the eligibility and suitability of the donor and the prospective parent to whom the germ line cells are donated in terms of the foregoing provisions, to keep a register with updated records thereof, and to inform the Authority without delay the full details of every donation.

(7) Whosoever uses, transfers or fertilises any germ line cells in contravention of this article shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than ten thousand euro (€10,000) and not exceeding twenty-three thousand euro (€23,000) or to imprisonment not exceeding five years or to both such fine and imprisonment:

Provided that where the person is a medical practitioner he shall be exempt from criminal liability where he shows that he took reasonable care to determine that the person from whom the germ line cells originated was a prospective parent or an eligible donor within the meaning of this Act.

(8) No person shall pay consideration to a donor or to any other person to arrange for the services of a donor or offer to pay such consideration:

Provided that oocytes donors may be compensated for the costs and expenses of the stimulation treatments."

Amendment of
article 12 of the
principal Act.

8. Article 12 of the principal Act shall be amended as follows:

(1) in sub-article (1) thereof:

(a) in paragraph (c):

(i) immediately after the words "a man" there shall be added the words "before or"; and

(ii) immediately after the words "after his death" there shall be added the words", except in the case where the deceased has donated his sperm";

(b) in paragraph (d):

(i) immediately after the words "a woman" there shall be added the word "before or"; and

(ii) immediately after the words "after her death" there shall be added the words ", except in the case where the deceased has donated her egg cells"; and

(2) sub-article (2) thereof shall be substituted by the following:

"(2) Nothing in this Act shall be construed or interpreted in a way as to impede, for medical reasons and according to accepted medical norms, the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage for the generation of an embryo."

9. Article 18 of the principal Act shall be amended as follows:

Amendment of
article 18 of the
principal Act.

(a) sub-article (1) thereof shall be substituted by the following:

"(1) The consent of the prospective parent or parents who are to have access to medically assisted procreation procedures is to be expressed in writing in such form, as may be prescribed by regulations under this Act also specifying whether they consent to cryo-preservation of any supernumerary embryos and whether they consent to the donation of embryos, if necessary, to and in the presence of the medical practitioner in charge of the procedure:

Provided that where the prospective parents are married or in a stable relationship, their consent shall be expressed jointly in writing in the prescribed form:

Provided further that when the prospective parent or prospective parents give their consent to cryo-preservation of any supernumerary embryos and for the donation of embryos if necessary, the medical practitioner in charge of the procedure shall implant up to a maximum of two embryos:

Provided further that when the prospective parent or prospective parents do not give their consent to the cryo-preservation of any supernumerary embryos and to the donation of fertilised eggs if necessary, the medical practitioner in charge of the procedure shall only fertilize up to a maximum of two eggs:

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Provided further that consent to cryo-preservation may only be withdrawn in writing by the prospective parent or prospective parents before fertilisation.";

(b) sub-article (2) thereof shall be amended as follows:

(i) for the words "both prospective parents" there shall be substituted the words "the prospective parent or prospective parents";

(ii) paragraph (f) thereof shall be substituted by the following:

"(f) the bioethical issues, including the cryo-preservation process involved as referred to in article 4 and article 7;"

(iii) in paragraph (g) thereof for the word "procedure." there shall be substituted the word "procedure;" and

(iv) immediately after paragraph (g) thereof, there shall be added the following new paragraph:

"(h) the circumstances in which the Authority may give for adoption embryos to a third party in terms of this Act."; and

(v) in sub-article (4) thereof, for the words "both prospective parents" there shall be substituted the words "the prospective parent or prospective parents".

Substitution of
article 19 of the
principal Act.

10. Article 19 of the principal Act shall be substituted by the following:

"Status of child
born.

19. (1) Any child born as a result of any medically assisted procreation procedure, including cases where the child was born from donated germ line cells or a donated embryo, shall be considered to be the child of the prospective parent or prospective parents who have expressed their consent in writing as provided in article 18 and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parent or prospective parents without the intervention of any procedure as aforesaid; and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status

as the direct descendant of such prospective parent or prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.

(2) There shall be no link of filiation between the child born from donated germ line cells or adopted embryos and the persons from whom donated germ line cells or adopted embryos originated."

11. Article 22 of the principal Act shall be substituted by the following:

Substitution of article 22 of the principal Act.

"Licence for premises.

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22. (1) No premises may be used for any activity related to medically assisted procreation unless the premises are licensed for the purpose by the Licensing Authority according to the Human Blood and Transplants Act and any regulations made thereunder.

(2) It shall be the duty of every licensee to keep a confidential register with full details of every medically assisted procreation procedure, germ line cell donation, cryo-preservation of germ line cells and cryo-preservation of embryos in terms of this Act and to pass on this information to the Authority without delay."

12. In paragraph (a) of sub-article (1) of article 115 of the Civil Code, for the words "not more than forty-five years" there shall be substituted the words "not more than forty-eight years".

Consequential amendment to article 115 of the Civil Code. Cap. 16.

13. In sub-regulation (1) of regulation 2 of the Leave for Medically Assisted Procreation National Standard Order the definition "prospective parents" shall be substituted by the following:

Consequential amendment to the Leave for Medically Assisted Procreation National Standard Order. S.L. 452.114.

Cap. 524.

" "prospective parent" means any person regardless of gender or sexual orientation, who has attained the age of majority and is a receptor or user of the medically assisted procreation techniques regulated under the Embryo Protection Act and for the purpose of these regulations shall also include oocytes donors;"

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Passed by the House of Representatives at Sitting No. 133 of the
19th June, 2018.

ANĠLU FARRUGIA
Speaker

RAYMOND SCICLUNA
Clerk of the House of Representatives

