

MALTA

ATT Nru XI tal-2022

ATT maħruġ b'liġi mill-Parlament ta' Malta.

ATT sabiex jemenda diversi liġijiet dwar il-Prokreazzjoni Assistita u sabiex jagħmel dispozizzjonijiet anċillari u konsegwenzjali għalihom.

ACT No. XI of 2022

AN ACT enacted by the Parliament of Malta.

AN ACT to amend various laws relating to Assisted Procreation and to make ancillary and consequential provisions thereto.

Nagħti l-kunsens tiegħi.

(L.S.)

FRANK BEZZINA
Aġent President

27 ta' Lulju, 2022

ATT Nru XI tal-2022

ATT sabiex jemenda diversi liġijiet dwar il-Prokreazzjoni Assistita u sabiex jagħmel dispożizzjonijiet ancillari u konsegwenzjali għalihom.

Il-PRESIDENT bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f'dan il-Parlament, u bl-awtorità tal-istess, hareġ b'liġi dan li ġej:-

1. (1) It-titolu fil-qosor ta' dan l-Att huwa l-Att tal-2022 li jemenda Diversi Liġijiet dwar il-Prokreazzjoni Assistita. Titolu fil-qosor u bidu fis-sehħ.

(2) Dan l-Att għandu jidhol fis-sehħ f'dik id-data jew dati li l-Ministru responsabbli għas-saħħa u l-Ministru responsabbli għall-politika soċjali jistgħu, b'avviż fil-Gazzetta, jistabbilixxu u jistgħu jiġu hekk stabbiliti dati differenti għal dispożizzjonijiet u, jew għanijiet differenti ta' dan l-Att.

TAQSIMA I
EMENDI GHALL-ATT DWAR IL-PROTEZZJONI TA'
EMBRIJUNI

Emendi għall-Att dwar il-Protezzjoni ta' Embrijuni. Kap. 524.

2. Din it-Taqsima temenda l-Att dwar il-Protezzjoni ta' Embrijuni u għandha tinqara u tinftiehem haġa waħda mal-Att dwar il-Protezzjoni ta' Embrijuni, hawn aktar 'il quddiem f'din it-Taqsima msejjaħ "l-Att prinċipali".

Emenda tal-artikolu 2 tal-Att prinċipali.

3. L-artikolu 2 tal-Att prinċipali għandu jiġi emendat b'dan li ġej:

(a) il-proviso għat-tifsira "donatur" tiegħu għandu jiġi sostitwit b'dan li ġej:

"Izda donazzjonijiet minn axxendent għal dixxendent, dixxendent għal axxendent, aħwa, sew jekk mill-istess ġenituri, sew jekk minn ġenitur wieħed biss, ma għandhomx ikunu permessi;" u

(b) it-tifsira "Protokoll" tiegħu għandha tiġi sostitwita b'dan li ġej:

" "Protokoll" tfisser il-Protokoll stabbilit bil-miktub mill-Awtorità u miġjub fis-seħh permezz ta' regolamenti magħmula mill-Ministru taħt dan l-Att, kif pubblikati fil-Gazzetta;"

Emenda tal-artikolu 4 tal-Att prinċipali.

4. L-artikolu 4 tal-Att prinċipali għandu jiġi emendat b'dan li ġej:

(a) fil-paragrafi (b) u (ċ) u fis-subparagrafu (i) tal-paragrafu (e) tas-subartikolu (1) tiegħu, minnufih wara l-kelma "Att" għandhom jiġu miżjuda l-kliem "u kwalunkwe regolamenti magħmula taħtu";

(b) fil-paragrafu (h) tas-subartikolu (1) tiegħu, il-kliem "taħt dan l-Att." għandhom jiġu sostitwiti bil-kliem "taħt dan l-Att;" u minnufih wara għandu jiġi miżjud dan il-paragrafu gdid li ġej:

"(i) sabiex tistabbilixxi u tmantni Protokoll bil-miktub, li għandu jikkonsisti fil-prinċipji regolatorji li għandhom jiġu segwiti fit-twettiq tal-funzjonijiet tagħha taħt dan l-Att:

Izda illi dan il-Protokoll għandu jiġi diskuss fil-Kumitat Permanenti dwar is-Saħħa fi żmien erba' (4)

gimghat mid-data tal-pubblikazzjoni tar-regolamenti msemmija fit-tifsira "Protokoll" fl-artikolu 2."; u

(ċ) minnufih wara t-tielet proviso għas-subartikolu (3) tiegħu għandu jiġi miżjud dan il-proviso ġdid li ġej:

"Iżda wkoll li l-Awtorità għandha tkun obbligata li ttipprovdi lill-ġenitur prospettiv jew ġenituri prospettivi l-informazzjoni medika u, jew dijanjostika dwar l-embrijun kif speċifikat fil-Protokoll imfisser fl-artikolu 2:".

5. L-artikolu 6 tal-Att prinċipali għandu jiġi emendat b'dan li ġej:

Emenda tal-artikolu 6 tal-Att prinċipali.

(a) fil-paragrafu (b) tiegħu l-kliem "aktar minn ħames ċelloli tal-bajd" għandhom jiġu sostitwiti bil-kliem "aktar ċelloli tal-bajd mill-ammont massimu stabbilit fil-Protokoll";

(b) fl-ewwel proviso għall-paragrafu (b) tiegħu l-kliem "u sa massimu ta' ħames ċelloli tal-bajd fertilizzat f'ċiklu ta' trattament wieħed sakemm dan isir skont Protokoll stabbilit bil-miktub mill-Awtorità. Dan il-Protokoll għandu jiġi diskuss fil-Kumitat Parlamentari dwar is-Saħħa sa erba' gimghat minn meta jiġi ppubblikat" għandhom jiġu sostitwiti bil-kliem "f'ċiklu ta' trattament wieħed (1) sakemm dan isir skont il-Protokoll";

(ċ) fit-tieni proviso għall-paragrafu (b) tiegħu minnufih wara l-kliem "ġenitur prospettiv" għandhom jiġu miżjud l-kliem "mingħand min originaw" u minnufih wara l-kliem "minn kwalunkwe trattament ta' prokreazzjoni assistita b'mod mediku preċedenti" għandhom jiġu miżjud l-kliem "ħlief f'dawk iċ-ċirkostanzi speċifikati fil-Protokoll u li jiksbu l-awtorizzazzjoni minn qabel tal-Awtorità, f'liema każ il-fertilizzazzjoni ta' iktar ċelloli tal-bajd għandu jkun permess"; u

(d) fil-paragrafu (e) tiegħu l-kliem "finijiet ewġeniċi;" għandhom jiġu sostitwiti bil-kliem "finijiet ewġeniċi:" u minnufih wara għandu jiġi miżjud dan il-proviso ġdid li ġej:

"Iżda l-Protokoll jista' jispeċifika li ċerti ċirkostanzi eċċezzjonali ma għandhomx jikkostitwixxu għażla ta' embrijuni għal skopijiet ewġeniċi; b'dana però wkoll li l-esperti mediċi kif elenkati fil-Protokoll għandhom jagħtu informazzjoni u tifsir dwar l-ittestjar ta' ċelloli tal-bajda umana (oocytes) u ttestjar ieħor li huwa disponibbli lill-ġenitur prospettiv jew il-ġenituri prospettivi, u l-imsemmija ġenitur prospettiv jew ġenituri prospettivi għandhom jagħzlu liema ttestjar għandu jsir wara konsultazzjoni mal-esperti

mediċi;".

Emenda tal-artikolu 7 tal-Att prinċipali.

6. Fis-subartikolu (5) tal-artikolu 7 tal-Att prinċipali l-kliem "Ġenitur prospettiv jew ġenituri prospettivi li, qabel ma daħal fis-seħħ dan l-Att, kellhom embrijuni krijo-preservati," għandhom jiġu sostitwiti bil-kliem "Ġenitur prospettiv jew ġenituri prospettivi li għandhom embrijuni krijo-preservati".

Emenda tal-artikolu 9 tal-Att prinċipali.

7. L-artikolu 9 tal-Att prinċipali għandu jiġi emendat b'dan li ġej:

(a) minnufih wara l-ewwel proviso għas-subartikolu (1) tiegħu għandu jiġi miżjud dan il-proviso ġdid li ġej:

"Iżda wkoll meta d-donatur ta b'donazzjoni ċ-ċelloli *germ line* lil stabbiliment tat-tessut awtorizzat barra minn Malta, skont l-Att dwar id-Demm Uman u t-Trapjanti, u dawn iċ-ċelloli *germ line* se jkunu distribwiti u, jew importati lejn stabbiliment tat-tessut f'Malta, għandu jkun iffirmit ftehim ta' parti terza bejn id-detentur tal-liċenzja Malti u d-detentur tal-liċenzja tal-istabbiliment tat-tessut barrani:";

Kap. 483.

(b) fis-subartikolu (3) tiegħu minnufih wara l-kliem "ta' sitta u tletin (36) sena" għandhom jiġu miżjuda l-kliem "fil-jum tad-donazzjoni";

(ċ) l-ewwel u t-tieni provisos għas-subartikolu (4) tiegħu għandhom jiġu sostitwiti bil-provisos ġodda li ġejjin:

"Iżda d-dokumenti mediċi li jistgħu jaffettwaw is-saħħa tal-wild u l-identità tad-donatur jew tal-persuni li minnhom ikun oriġina embrijun adottat għandhom ikunu aċċessibbli għall-wild konċepit miċ-ċelloli *germ line* tal-imsemmi donatur meta l-wild jagħlaq it-tmintax (18)-il sena u, bil-kunsens tal-Awtorità, id-dokumenti mediċi li jistgħu jaffettwaw is-saħħa tal-wild għandhom ikunu aċċessibbli għall-ġenitur jew ġenituri f'xi stadju qabel f'ċirkostanzi eċċezzjonali fejn il-ħajja jew is-saħħa tal-wild li twieled minn dawk iċ-ċelloli *germ line* tkun fil-periklu:

Iżda wkoll l-Awtorità għandha żżomm id-dokumenti dwar l-identità tad-donatur għall-perjodu ta' ħamsa u sittin (65) sena:";

(d) minnufih wara s-subartikolu (5) tiegħu għandu jiġi

miżjud dan is-subartikolu ġdid li ġejj:

"(5A) Ċelloli *germ line* krijo-preservati li ma jintużawx f'Malta jistgħu jiġu esportati u, jew distribwiti lill-istabbilimenti tat-tessuti barra minn Malta:

Iżda wkoll illi l-esportazzjoni u, jew distribuzzjoni taċ-ċelloli *germ line* lill-istabbilimenti tat-tessuti barra minn Malta għandha tkun irregistrata b'mod li jkun assigurat li jkunu traċċabbli u li dan ir-reġistru għandu jkun mibgħut lill-Awtorità mingħajr dewmien."; u

(e) fis-subartikolu (6) tiegħu minnufih wara l-kliem "li żżomm reġistru b'notamenti aġġornati," għandhom jiġu miżjuda l-kliem "li jinkludi reġistru traċċabbli għad-donaturi".

8. Il-proviso għas-subartikolu (3) tal-artikolu 15 tal-Att prinċipali għandu jiġi sostitwit b'dan il-proviso ġdid li ġejj:

Emenda tal-artikolu 15 tal-Att prinċipali.

"Iżda xejn f'dan is-subartikolu bl-ebda mod ma għandu jiġi interpretat bħala li jipprojbixxi interventi kliniċi meqjusa permissibbli skont il-Protokoll, u lanqas li jipprojbixxi lill-ġenitur prospettiv u, jew ġenituri prospettivi milli jagħżel jew jagħzlu l-krijo-preservazzjoni tal-embrijun uman wara li jitwettag kwalunkwe minn dawn l-interventi fejn din l-għażla tkun meqjusa permissibbli skont il-Protokoll."

9. L-artikolu 23 tal-Att prinċipali għandu jiġi emendat b'dan li ġejj:

Emenda tal-artikolu 23 tal-Att prinċipali.

(a) l-artikolu 23 tal-Att prinċipali fl-intier tiegħu għandu jiġi enumerat mill-ġdid bħala s-subartikolu (1) tiegħu;

(b) fil-paragrafu (ċ) tas-subartikolu (1) tiegħu, kif enumerat mill-ġdid, il-kliem "assistita b'mod mediku." għandhom jiġu sostitwiti bil-kliem "assistita b'mod mediku;" u minnufih wara għandu jiġi miżjud dan il-paragrafu ġdid li ġejj:

"(d) jippromulga jew iġib fis-seħħ kwalunkwe Protokoll imsemmi f'dan l-Att u sabiex jirrevoka, jemenda jew ivarja l-istess."; u

(ċ) minnufih wara s-subartikolu (1) tiegħu, kif enumerat mill-ġdid, għandu jiġi miżjud dan is-subartikolu ġdid li ġejj:

"(2) Il-Protokoll maħruġ fit-termini ta' dan l-Att jista' jiġi ppubblikat bl-ilsien Ingliż biss."

TAQSIMA II
EMENDA GHALL-ATT DWAR L-AMMINISTRAZZJONI TAL-ADOZZJONI

Emendi għall-Att dwar l-Amministrazzjoni tal-Adozzjoni. Kap. 495.

10. Din it-Taqsima temenda l-Att dwar l-Amministrazzjoni tal-Adozzjoni u għandha tinqara u tinftiehem haġa waħda mal-Att dwar l-Amministrazzjoni tal-Adozzjoni, hawn iżjed 'il quddiem f'din it-Taqsima msejjaħ "l-Att prinċipali".

Emenda tal-artikolu 4 tal-Att prinċipali.

11. Fil-paragrafu (g) tas-subartikolu (1) tal-artikolu 4 tal-Att prinċipali, il-kliem "tad-dispożizzjonijiet ta' dan l-Att u ta' kull regolament li jsir tahtu." għandhom jiġu sostitwiti bil-kliem "tad-dispożizzjonijiet ta' dan l-Att u ta' kull regolament li jsir tahtu;" u minnufih wara għandu jiġi miżjud dan il-paragrafu ġdid li ġej:

Kap. 524.

"(h) li jagħmel ir-rakkomandazzjonijiet lill-Awtorità għall-Protezzjoni tal-Embrijuni dwar l-eligibilità u s-sostenibbiltà ta' ġenitur jew ġenituri prospettivi relatat mal-adozzjoni ta' embrijun kif provdut fis-subartikolu (4) tal-artikolu 4 tal-Att dwar il-Protezzjoni ta' Embrijuni."

Mgħoddi mill-Kamra tad-Deputati fis-Seduta Nru 26 tas-6 ta' Lulju, 2022.

ANĠLU FARRUGIA
Speaker

RAYMOND SCICLUNA
Skrivan tal-Kamra tad-Deputati

I assent.

(L.S.)

FRANK BEZZINA
Acting President

27th July, 2022

ACT No. XI of 2022

AN ACT to amend various laws relating to Assisted Procreation and to make ancillary and consequential provisions thereto.

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 Various Laws relating to Assisted Procreation (Amendment) Act, 2022.

Short title and commencement.

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

PART I
AMENDMENTS TO THE EMBRYO PROTECTION ACT

Amendments to the Embryo Protection Act. Cap. 524.

2. This Part amends the Embryo Protection Act and it shall be read and construed as one with the Embryo Protection Act, hereinafter in this Part referred to as "the principal Act".

Amendment of article 2 of the principal Act.

3. Article 2 of the principal Act shall be amended by the following:

(a) the proviso to the definition "donor" thereof shall be substituted by the following:

"Provided that donations by an ascendant to a descendant, descendant to an ascendant, from sibling to sibling, whether of the full or half-blood, shall not be permissible;" and

(b) the definition "Protocol" thereof shall be substituted by the following:

" "Protocol" means the Protocol established in writing by the Authority and brought into force by regulations made by the Minister under this Act, as published in the Gazette;"

Amendment of article 4 of the principal Act.

4. Article 4 of the principal Act shall be amended by the following:

(a) in paragraphs (b) and (c) and sub-paragraph (i) of paragraph (e) of sub-article (1) thereof, immediately after the word "Act" there shall be added the words "and any regulations made thereunder";

(b) in paragraph (h) of sub-article (1) thereof, the words "under this Act." shall be substituted by the words "under this Act;" and immediately thereafter there shall be added the following new paragraph:

"(i) to establish and maintain a Protocol in writing, which shall consist of the regulatory principles that shall be followed in carrying out its functions under this Act:

Provided that such Protocol shall be discussed in the Standing Committee on Health within four (4) weeks from the date of publication of the regulations referred to in the definition "Protocol" in article 2.;" and

(c) immediately after the third proviso to sub-article (3)

thereof there shall be added the following new proviso:

"Provided further that the Authority shall be obliged to provide the prospective parent or prospective parents with medical and, or diagnostic information concerning the embryo as specified in the Protocol defined in article 2:".

5. Article 6 of the principal Act shall be amended by the following: Amendment of article 6 of the principal Act.

(a) in paragraph (b) thereof the words "more than five egg cells" shall be substituted by the words "more egg cells than the maximum amount established by the Protocol";

(b) in the first proviso to paragraph (b) thereof the words "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" shall be substituted by the words "within one (1) treatment cycle provided that this is done in accordance with the Protocol";

(c) in the second proviso to paragraph (b) thereof immediately after the words "prospective parent" there shall be added the words "from whom they originate" and immediately after the words "from any prior medically assisted procreation treatments" there shall be added the words "except in those instances which may be specified in the Protocol and with the prior authorisation of the Authority, in which case, the fertilisation of more egg cells shall be permissible"; and

(d) in paragraph (e) thereof the words "eugenic purposes;" shall be substituted by the words "eugenic purposes:" and immediately thereafter there shall be added the following new proviso:

"Provided that the Protocol may specify that certain exceptional circumstances shall not constitute selection of embryos for eugenic purposes; provided, however, also that the medical experts as listed in the Protocol shall provide information and explanations relating to the testing of human egg cells (oocytes) and other testing which is available to the prospective parent or prospective parents and the said prospective parent or prospective parents shall decide which testing shall be carried out after consulting with the medical experts;".

A 300

Amendment of article 7 of the principal Act.

6. In sub-article (5) of article 7 of the principal Act the words "A prospective parent or prospective parents, who prior to the coming into force of this Act, have cryo-preserved embryos" shall be substituted by the words "A prospective parent or prospective parents who have cryo-preserved embryos".

Amendment of article 9 of the principal Act.

7. Article 9 of the principal Act shall be amended by the following:

(a) immediately after the first proviso to sub-article (1) thereof there shall be added the following new proviso:

Cap. 483. "Provided further that where the donor has donated the germ line cells in a tissue establishment abroad in accordance with the Human Blood and Transplants Act and these germ line cells are to be distributed and, or imported to a tissue establishment in Malta, there shall be a third-party agreement signed between the Maltese licensee and the licensee of the foreign tissue establishment:";

(b) in sub-article (3) thereof immediately after the words "of thirty-six (36)" there shall be added the words "years on day of donation";

(c) the first and second provisos to sub-article (4) thereof shall be substituted by the following new provisos:

"Provided that the medical records that may affect the health of the child and the identity of the donor or of the persons from whom an adopted embryo originated shall be accessible to the child conceived from the germ line cells of such donor upon the child reaching eighteen (18) years of age and, subject to the consent of the Authority, the medical records that may affect the health of the child shall be accessible to the parent or parents 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 traceable to the identity of the donor for a period of sixty-five (65) years:";

(d) immediately after sub-article (5) thereof there shall be added the following new sub-article:

"(5A) Cryo-preserved germ line cells which have not been used in Malta may be exported and, or distributed to tissue establishments abroad:

Provided further that the exportation and, or distribution of germ line cells to tissue establishments abroad shall be recorded in such a way as to ensure their traceability and such record shall be forwarded to the Authority without delay."; and

(e) in sub-article (6) thereof immediately after the words "to keep a register with updated records thereof," there shall be added the words "including the records traceable to the donors".

8. The proviso to sub-article (3) of article 15 of the principal Act shall be substituted by the following new proviso:

Amendment of article 15 of the principal Act.

"Provided that nothing in this sub-article shall in any way be construed as prohibiting clinical interventions deemed permissible in terms of the Protocol, nor prohibiting the prospective parent and, or prospective parents from opting for the cryopreservation of the human embryo after the carrying out of any such intervention wherever such an option is deemed permissible in terms of the Protocol."

9. Article 23 of the principal Act shall be amended by the following:

Amendment of article 23 of the principal Act.

(a) article 23 of the principal Act, in its entirety, shall be renumbered as sub-article (1) thereof;

(b) in paragraph (c) of sub-article (1) thereof, as renumbered, the words "medically assisted procreation." shall be substituted by the words "medically assisted procreation;" and immediately thereafter there shall be added the following new paragraph:

"(d) enact or to bring into force any Protocol referred to in this Act and to revoke, amend or vary the same."; and

(c) immediately after sub-article (1) thereof, as renumbered, there shall be added the following new sub-article:

"(2) The Protocol issued in terms of this Act may be published in the English language only."

A 302

PART II
AMENDMENT TO THE ADOPTION ADMINISTRATION ACT

Amendment to
the Adoption
Administration
Act.
Cap. 495.

10. This Part amends the Adoption Administration Act and shall be read and construed as one with the Adoption Administration Act, hereinafter in this Part referred to as "the principal Act".

Amendment of
article 4 of the
principal Act.

11. In paragraph (g) of sub-article (1) of article 4 of the principal Act, the words "any regulations made thereunder." shall be substituted by the words "any regulations made thereunder;" and immediately thereafter there shall be added the following new paragraph:

"(h) making recommendations to the Embryo Protection Authority regarding the eligibility and suitability of prospective parent or parents relative to adoption of an embryo as provided in sub-article (4) of article 4 of the Embryo Protection Act."

Cap. 524.

Passed by the House of Representatives at Sitting No. 26 of the 6th July, 2022.

ANĠLU FARRUGIA
Speaker

RAYMOND SCICLUNA
Clerk of the House of Representatives

VERŻJONI ELETTRONIKA