Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

Directions and guidance

24 Directions as to particular matters.

(1) If, in the case of any information about persons for whom treatment services[^1^, other than basic partner treatment services], were provided, the person responsible does not know that any child was born following the treatment, the period specified in directions by virtue of section 13(4) of this Act shall not expire less than 50 years after the information was first recorded.

(2) In the case of every licence under paragraph 1[^2^ or 1A] of Schedule 2 to this Act, directions shall require information to be recorded and given to the Authority about each of the matters referred to in section 13(2)(a) to (e) of this Act.

(3) In relation to gametes or embryos that are not intended for human application,[^3^] directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises.

[^3^](3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage—

(a) between premises to which licences relate,
(b) between such premises and relevant third party premises,
(c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or
(d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to directions given under subsection (4),

in such circumstances and subject to such conditions as may be specified in the directions.]

[F5(3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.]

(4) Directions may authorise any person to whom a licence applies to receive gametes[F6, embryos or human admixed embryos] from outside the United Kingdom or to send gametes[F6, embryos or human admixed embryos] outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

[F7(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to[F8 export from the United Kingdom to a third country], gametes or embryos intended for human application, the Authority shall—

(a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such[F9]... exports meet standards of quality and safety equivalent to those laid down in this Act, and

(b) have regard to ensuring traceability.]

[F10(4AA) Directions must, in accordance with paragraph 1 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make qualifying imports (other than a one-off import) must comply before the Authority gives any directions under subsection (4) authorising the person to make qualifying imports.

(4AB) Directions must, in accordance with paragraph 2 of Schedule 3AA, specify requirements with which any person to whom a licence applies who proposes to make a qualifying import which is a one-off import must comply before the Authority gives any directions under subsection (4) authorising the person to make the import.

(4AC) In giving any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, the Authority must include the directions specified in paragraph 3 of Schedule 3AA.

(4AD) Where the Authority gives any directions under subsection (4) authorising any person to whom a licence applies to make any qualifying imports, it must provide that person with a certificate in the form set out in Annex II to the fourth Directive.

(4AE) In subsections (4AA) and (4AB) a reference to a one-off import, in relation to gametes or embryos, is to gametes or embryos imported for the purposes of providing services to a particular person or persons on one occasion only.

(4AF) In subsections (4AA) to (4AD) and Schedule 3AA “qualifying import” means the import into the United Kingdom from a third country of gametes or embryos intended for human application.]

[F11(4B) Regulations may make provision requiring or authorising the giving of directions in relation to particular matters which are specified in the regulations and relate to
activities falling within section 4A(2) (activities involving genetic material of animal origin).]

[F12(5A) Directions may make provision for the purpose of dealing with a situation arising in consequence of—
(a) the variation of a licence, or
(b) a licence ceasing to have effect.

(5B) Directions under subsection (5A)(a) may impose requirements—
(a) on the holder of the licence,
(b) on the person who is the person responsible immediately before or immediately after the variation, or
(c) on any other person, if that person consents.

(5C) Directions under subsection (5A)(b) may impose requirements—
(a) on the person who holds the licence immediately before the licence ceases to have effect,
(b) on the person who is the person responsible at that time, or
(c) on any other person, if that person consents.

(5D) Directions under subsection (5A) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.

(5E) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (5A) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.]

(11) Where the Authority proposes to give directions specifying any animal for the purposes of paragraph 1(1)(f) or 3(2) of Schedule 2 to this Act, it shall report the proposal to the Secretary of State; and the directions shall not be given until the Secretary of State has laid a copy of the report before each House of Parliament.

[F14F15(12) Directions must specify the systems to be adopted for the identification of gametes and embryos intended for human application which the Authority considers appropriate to secure compliance with the requirements of —
(a) paragraph 1 of Article 25 of the first Directive (coding of information),
(b) paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article,
(c) Article 10a of the third Directive (format of the Single European Code), and
(d) paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).]

[F16(12A) Directions must require information to be provided to the Authority which the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive (European coding system).]

(13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of—
(a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application,
(b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or

c) any misidentification or mix-up of gametes or embryos intended for human application.

(14) In this section, “tissue establishment” has the meaning given by Article 3(o) of the first Directive.

Annotations:

Amendments (Textual)

F1 Words in s. 24(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(2)

F2 Words in s. 24(2) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(3)

F3 Words in s. 24(3) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(4)

S. 24(3A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(5)

F5 S. 24(3B) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 22(2), 68(2); S.I. 2009/2232, art. 2(j)

F6 Words in s. 24(4) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 22(3), 68(2); S.I. 2009/2232, art. 2(j)

F7 S. 24(4A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(6)

F8 Words in s. 24(4A) substituted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), 5(4)(a)(i)


F10 S. 24(4AA)-A(4AF) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), 5(4)(b)

F11 S. 24(4B) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 22(4), 68(2); S.I. 2009/2232, art. 2(j)

F12 S. 24(5A)-(5E) substituted for s. 24(5)-(10) (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 22(5), 68(2); S.I. 2009/2232, art. 2(j)

F13 Word in s. 24(11) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), ss. 22(6), 68(2); S.I. 2009/2232, art. 2(j)

F14 S. 24(12)-(14) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(7)

F15 S. 24(12) substituted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), 4(2) (with reg. 6(2)-(6))

F16 S. 24(12A) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Fertilisation and Embryology (Amendment) Regulations 2018 (S.I. 2018/334), regs. 1(3), 4(3) (with reg. 6(2)(3))

Commencement Information

I1 S. 24 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)
Changes to legislation:
Human Fertilisation and Embryology Act 1990, Section 24 is up to date with all changes known to be in force on or before 11 May 2019. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

<table>
<thead>
<tr>
<th>Changes and effects yet to be applied to:</th>
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<tbody>
<tr>
<td>– s. 24(3A)(c) omitted by S.I. 2019/482 reg. 2(12)(a)(i)</td>
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<tr>
<td>– s. 24(3A)(d) words substituted by S.I. 2019/482 reg. 2(12)(a)(ii)</td>
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<tr>
<td>– s. 24(4AD) words substituted by S.I. 2019/482 reg. 2(12)(b)</td>
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<td>– s. 24(14) omitted by S.I. 2019/482 reg. 2(12)(d)</td>
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Changes and effects yet to be applied to the whole Act associated Parts and Chapters:
Whole provisions yet to be inserted into this Act (including any effects on those provisions):

| – s. 2A(1A) inserted by S.I. 2019/482 reg. 2(4) |
| – s. 42A inserted by S.I. 2019/482 reg. 2(14) |
| – Sch. 3 para. A1 inserted by S.I. 2019/482 reg. 2(17)(a) |
| – Sch. 3A para. 11A-11C and cross-heading inserted by S.I. 2019/482 reg. 2(17)(c) |
| – Sch. 3AA para. A1 and cross-heading inserted by S.I. 2019/482 reg. 2(18)(a) |
| – Sch. 3AA para. 3A and cross-headings inserted by S.I. 2019/482 reg. 2(18)(c) |