



# Human Fertilisation and Embryology Act 1990

## 1990 CHAPTER 37

### *Directions and guidance*

#### **23 Directions: general.**

- (1) The Authority may from time to time give directions for any purpose for which directions may be given under this Act or directions varying or revoking such directions.
- (2) A person to whom any requirement contained in directions is applicable shall comply with the requirement.
- (3) Anything done by a person in pursuance of directions is to be treated for the purposes of this Act as done in pursuance of a licence.
- (4) Where directions are to be given to a particular person, they shall be given by serving notice of the directions on the person.
- (5) In any other case, directions may be given—
  - [<sup>F1</sup>(a) in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person—
    - (i) who is the person responsible or the holder of the licence, if different, or
    - (ii) who was the person responsible or the holder of the licence, if different,]
    - (b) if the directions appear to the Authority to be general directions or it appears to the Authority that it is not practicable to give notice in pursuance of paragraph (a) above, by publishing the directions in such way as, in the opinion of the Authority, is likely to bring the directions to the attention of the persons to whom they are applicable.

<sup>F2</sup>(6) .....

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*Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Directions and guidance. (See end of Document for details)*

#### Textual Amendments

- F1** S. 23(5)(a) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), s. 68\(2\), Sch. 7 para. 9\(a\), Sch. 8 Pt. 1; S.I. 2009/2232, art. 2\(y\)](#)
- F2** S. 23(6) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\), s. 68\(2\), Sch. 7 para. 9\(b\), Sch. 8 Pt. 1; S.I. 2009/2232, art. 2\(y\)](#)

#### Commencement Information

- I1** S. 23 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

## 24 Directions as to particular matters.

- (1) If, in the case of any information about persons for whom treatment services<sup>[F3]</sup>, 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 <sup>[F4]</sup>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) <sup>[F5]</sup>In relation to gametes or embryos that are not intended for human application,] 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.
- <sup>[F6]</sup>(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—
- between premises to which licences relate,
  - between such premises and relevant third party premises,
  - 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
  - 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.]
- <sup>[F7]</sup>(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<sup>[F8]</sup>, embryos or human admixed embryos] from outside the United Kingdom or to send gametes<sup>[F8]</sup>, embryos or human admixed embryos] outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions,

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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.

[<sup>F9</sup>(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to [<sup>F10</sup>import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country][<sup>F10</sup>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 [<sup>F11</sup>imports or] exports meet standards of quality and safety equivalent to those laid down in this Act, and
- (b) have regard to ensuring traceability.]

[<sup>F12</sup>(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.]

[<sup>F13</sup>(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).]

[<sup>F14</sup>(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.

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- (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 <sup>F15</sup>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.
- <sup>F16</sup>(12) <sup>F17</sup>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).]
- <sup>F18</sup>(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.]

#### Textual Amendments

- F3** 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)**
- F4** 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)**

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- F5** 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)**
- F6** 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)**
- F7** 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)
- F8** 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)
- F9** 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)**
- F10** 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)**
- F11** Words in s. 24(4A)(a) omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of [The Human Fertilisation and Embryology \(Amendment\) Regulations 2018 \(S.I. 2018/334\)](#), regs. 1(3), **5(4)(a)(ii)**
- F12** S. 24(4AA)-(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)**
- F13** 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)
- F14** 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)
- F15** 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)
- F16** 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)**
- F17** 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))
- F18** 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

- I2** S. 24 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

## 25 Code of practice.

- (1) The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.
- (2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child's need for <sup>F19</sup>supportive parenting), and of other children who may be affected by such births.

<sup>F20</sup>(2A) The code shall also give guidance about—

- (a) the giving of a suitable opportunity to receive proper counselling, and
- (b) the provision of such relevant information as is proper,

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in accordance with any condition that is by virtue of section 13(6) or (6A) a condition of a licence under paragraph 1 of Schedule 2.]

- (3) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.
- (4) The Authority may from time to time revise the whole or any part of the code.
- (5) The Authority shall publish the code as for the time being in force.
- (6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but—
  - (a) [<sup>F21</sup>the Authority] shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be “proper” or “suitable”, take account of any relevant provision of the code, and
  - (b) [<sup>F22</sup>the Authority] may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance of or failure to observe the provisions of the code.

#### Textual Amendments

- F19** Words in s. 25(2) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 23(2)**, 68(2); S.I. 2009/2232, art. 2(j)
- F20** S. 25(2A) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 23(3)**, 68(2); S.I. 2009/2232, art. 2(j)
- F21** Words in s. 25(6)(a) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 23(4)**, 68(2); S.I. 2009/2232, art. 2(j)
- F22** Words in s. 25(6)(b) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 23(4)**, 68(2); S.I. 2009/2232, art. 2(j)

#### Commencement Information

- I3** S. 25 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400](#), **art. 2(2)**

## 26 Procedure for approval of code.

- (1) The Authority shall send a draft of the proposed first code of practice under section 25 of this Act to the Secretary of State within twelve months of the commencement of section 5 of this Act.
- (2) If the Authority proposes to revise the code or, if the Secretary of State does not approve a draft of the proposed first code, to submit a further draft, the Authority shall send a draft of the revised code or, as the case may be, a further draft of the proposed first code to the Secretary of State.
- (3) Before preparing any draft, the Authority shall consult such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate.
- (4) If the Secretary of State approves a draft, he shall lay it before Parliament and, if he does not approve it, he shall give reasons to the Authority.
- (5) A draft approved by the Secretary of State shall come into force in accordance with directions.

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**Changes to legislation:**

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