STATUTORY INSTRUMENTS

2012 No. 1501

HUMAN TISSUE

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

Made - - - - 11th June 2012

Laid before Parliament 14th June 2012

Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to health protection measures regulating the use of material of human origin [M1].

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, as read with paragraph 1A of Schedule 2 to, the European Communities Act 1972 [M2].

It appears to the Secretary of State that it is expedient for the reference to part B of the Annex to Directive 2010/53/EU of 7th July 2010 of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation [M3] to be construed as a reference to that Annex as amended from time to time.

Marginal Citations

M1 *See*S.I. 2004/3037.

M2 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51).

M3 OJ No. L 207, 6.08.10, p.14; as corrected by a corrigendum made on 6th August 2010 (OJ No. L 243, 16.09.2010, p.68).

PART 1

Citation, commencement and extent

Citation and commencement

1.—(1) These Regulations may be cited as the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

(2) Except as provided under paragraph (3), these Regulations come into force on 27th August 2012.

(3) These Regulations come into force on 12th July 2012 so far as necessary to enable anything to be done for the purposes of granting, refusing or reconsidering licence applications, or varying, suspending or revoking licences in respect of activities required by virtue of these Regulations to be authorised by a licence from 27th August 2012, including but not limited to—

(a) giving directions under section 23(1) of, or paragraph 2(4)(c) to (f) of Schedule 3 to, the 2004 Act;

(b) publishing guidance under regulation 12;

(c) establishing the Framework under regulation 13; and

(d) the fixing of fees.

Extent

2.—(1) Subject to paragraphs (2) and (3), these Regulations extend to England and Wales, Northern Ireland and Scotland.

(2) Regulation 25(2), (3), (4) and (7) extends to England and Wales and Northern Ireland only.

(3) Regulation 29 extends to Scotland only.

PART 2

Interpretation and designation of the competent authority

Interpretation

3.—[F1**](1)]** In these Regulations—

"the 2004 Act" means the Human Tissue Act 2004 ;

"the 2006 Regulations" means the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 ;

"the 2006 Scotland Act" means the Human Tissue (Scotland) Act 2006 ;

"the 2006 Scotland Regulations" means the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 ;

"the 2007 Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ;

"the Authority" means the Human Tissue Authority established under section 13 of the 2004 Act;

"consent", in respect of a donor, means **[**F2**]**, where retrieval of an organ takes place**]** —

(a) in England **[**F3**]**or**]** Northern Ireland, appropriate consent as defined in the 2004 Act ; F4...

(b) in Scotland, the authorisation referred to in Part 1 (transplantation etc.) of the 2006 Scotland Act or, as the case may be, the authorisation or lack of unwillingness of the donor referred to in the 2006 Scotland Regulations **[**F5**]**; or

(c) in Wales, express consent where that is required under any of sections 4 to 7 of the Human Transplantation (Wales) Act 2013 or, where express consent is not required, deemed consent under section 4 or 9 of that Act;**]**

"the Directive " means Directive 2010/53/EU of the European Parliament and of the Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation **[**F6, as it applies in relation to Northern Ireland**]**;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for the purposes of transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of relevant information on the characteristics of the donor needed to evaluate the donor's suitability for donation, in order to undertake a risk assessment and to minimise the risks for the recipient, and optimise organ allocation;

[F7"the Implementing Directive" means Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation **[**F8, as it applies in relation to Northern Ireland;**]]**

"licensed activity", in relation to a licence, means an activity which the licence authorises under Schedule 1;

"licence holder" means a person who holds a licence under Schedule 1;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy; and a part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability for transplantation, in order to undertake a risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which a donated organ becomes available for transplantation;

"procurement activity" means all or any of the following activities, undertaken for the purposes of procurement—

(a) donor characterisation;

(b) organ characterisation;

(c) preservation of an organ;

(d) making arrangements to transport an organ;

(e) retrieval of an organ;

[F9"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the Authority;**]**

"recipient" means a person who receives a transplant of an organ;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a

communicable disease, to death or life-threatening, disabling or incapacitating conditions for a patient or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to—

(a) identify the donor and the licence holder who retrieved the organ from the donor;

(b) identify the licence holder who implanted the organ in the recipient;

(c) identify the recipient at the premises at which the organ is implanted into the recipient; and

(d) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;

"transplantation" means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient; and

"transplantation activity" means all or any of the following activities, undertaken for the purposes of transplantation—

(a) organ characterisation;

(b) preservation of an organ;

(c) making arrangements to transport an organ;

(d) implantation of an organ.

[[F10](2) In these Regulations, as they apply in relation to Great Britain, a reference to ensuring compliance with these Regulations includes a reference to ensuring compatibility with the principles set out in Article 13 of Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation as modified by section 32(3C) of the 2004 Act.**]**

F1 Reg. 3 renumbered as reg. 3(1) (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 3 inserted (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(a)**

F3 Word in reg. 3 substituted (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(b)(i)**

F4 Word in reg. 3 omitted (coming into force in accordance with art. 1(2) of the amending S.I.) by virtue of The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(b)(ii)**

F5 Words in reg. 3 added (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(c)**

F6 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(i)** (as substituted by S.I. 2020/1305, regs. 1, **4(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 3 inserted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **3**

F8 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(ii)** (as substituted by S.I. 2020/1305, regs. 1, **4(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Reg. 3(2) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(c)** (as amended by S.I. 2020/1305, regs. 1, **4(c)**); 2020 c. 1, Sch. 5 para. 1(1)

[F11Designation of the competent authority

4. In relation to Northern Ireland, the Authority is designated the competent authority for the purposes of the Directive.**]**

F11 Reg. 4 substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(3)** (as substituted by S.I. 2020/1305, regs. 1, **5**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 3

Licensing

Licensing requirement

5.—(1) No person shall carry out a procurement activity or a transplantation activity otherwise than under the authority of a licence under Schedule 1.

(2) The authority conferred by a licence extends to the licence holder, any person designated by the licence holder and any person acting under the supervision of either of them.

(3) The Authority shall specify in the licence which procurement activity or transplantation activity a person may undertake under the licence.

(4) The Authority shall permit a person making an application for two or more—

(a) procurement activities;

(b) transplantation activities; or

(c) procurement activities and transplantation activities, to make single application in respect of the activities,

to make a single application in respect of the activities.

(5) Schedule 1 has effect.

[F12(6) Schedule 1A (which specifies information to be collected in certain circumstances for the purposes of paragraph 5 of Schedule 1) has effect.**]**

F12 Reg. 5(6) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Application of the 2004 Act in relation to licences under Schedule 1

6.—(1) The provisions of the 2004 Act referred to in paragraph (2) shall apply, subject to the modifications specified in **[**F13paragraphs (4) and (5)**]**, in relation to a licence under Schedule 1 to these Regulations as they apply to licences under paragraph 1 of Schedule 3, (licences for the purposes of section 16) to that Act.

(2) The provisions are—

(a) section 19(1), (2), (5) and (7) (right to reconsideration of licensing decisions);

(b) sections 20 to 24 (which relate to appeals and powers to give directions);

(c) section 37(1) to (5) (directions); and

(d) paragraphs 2(4)(c) to (f) and (5), 5, 7 to 11, and 13 of Schedule 3 (licences for the purposes of section 16).

(3) In their application by virtue of this regulation, those provisions extend to Scotland (as well as to the rest of the United Kingdom).

(4) In their application by virtue of this regulation—

(a) section 19 (right to reconsideration of licensing decisions) shall apply as if in subsection (2) the words ", or designated individual," were omitted F14...;

(b) section 23 (conduct of licensed activities) shall apply as if subsection (1) were limited to directions that the Authority considers necessary to ensure compliance with **[**F15these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland**]**;

(c) section 24 (changes of licence circumstance) shall apply as if subsection (1) were limited to directions that the Authority considers necessary to ensure compliance with **[**F15these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland**]** and as if for subsections (2)(b) and (3)(b) there were substituted—

"(b) on any other person who has authority to act under the licence;";

(d) section 37 (directions) shall apply—

(i) as if the reference in subsection (1) to "this Part" were to these Regulations; and

(ii) as if any reference in subsection (5) to a licence were to a licence under Schedule 1 to these Regulations;

(e) paragraph 2(4)(c) to (f) and 5 (characteristics of licence) of Schedule 3 shall apply as if it were limited to directions that the Authority considers necessary to ensure compliance with **[**F15these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland**]**;

(f) paragraph 7 (power to revoke licence) of that Schedule shall apply as if sub-paragraphs (1)(b) and (2)(b), (e) and (f) were omitted and as if for sub-paragraph (2)(b) there were substituted —

"(b) if it is satisfied that the licence holder has failed to discharge, or is unable because ofincapacity to discharge, any of its duties,";

(g) paragraph 8 (power to vary licence) of that Schedule shall apply as if sub-paragraphs (1), (2)(b), (3) and (4) were omitted;

(h) paragraph 9 (power to suspend licence) of that Schedule shall apply as if for sub-paragraph (3) there were substituted the following sub-paragraph—

"(3) Notice under sub-paragraph (1) shall be given to the licence holder or to any otherperson who has authority to act under the licence.";

(i) paragraph 10 (procedure in relation to licensing decisions) of that Schedule shall apply as if sub-paragraph (2)(b) were omitted; and

(j) paragraph 11 (notification of licensing decisions) of that Schedule shall apply as if sub-paragraphs (1)(b) and (3)(b) were omitted and as if for sub-paragraphs (2)(b) and 4(b) there were substituted—

"(b) any other person who has authority to act under the licence.";

(5) In its application by virtue of this regulation, section 22 (appeal on a point of law) of the 2004 Act is to have effect in Scotland as if the reference to the High Court were a reference to the Court of Session.

F13 Words in reg. 6(1) substituted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **4(a)**

F14 Words in reg. 6(4)(a) omitted (14.7.2014) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **4(b)**

F15 Words in reg. 6 substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(5)** (as substituted by S.I. 2020/1305, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

Extension of other provisions of the 2004 Act to Scotland

7.—(1) The following provisions shall extend to Scotland (as well as to the rest of the United Kingdom), so far as they relate to activities within section 14(1)(i) of the 2004 Act—

(a) section 14 (remit of the Human Tissue Authority); and

(b) section 15(a), (b), (d), (e) and (f) (general functions), subject to the modifications in paragraph (2).

(2) In its application by virtue of paragraph (1) section 15(e) and (f) of the 2004 Act is to be read as including a reference to advising the Scottish Ministers.

Breach of requirement to hold a licence

8.—(1) A person who contravenes regulation 5(1) commits an offence unless that person reasonably believes that—

(a) the activity being undertaken is not an activity to which regulation 5(1) applies; or

(b) they are acting under the authority of a licence under Schedule 1.

(2) A person guilty of an offence under paragraph (1) shall be liable—

(a) on summary conviction to a fine not exceeding the statutory maximum; or

(b) on conviction on indictment—

(i) to imprisonment for a term not exceeding 2 years,

(ii) to a fine, or

(iii) to both.

Preconditions to grant of a licence

9.—(1) The Authority may not grant a licence under Schedule 1 unless the following requirements are met.

(2) The Authority must be satisfied that the applicant—

(a) meets the relevant conditions in Schedule 1 and will continue to do so; and

(b) meets any other conditions or requirements that the Authority has imposed.

(3) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by, the applicant for the licence.

Duty of the licence holder

10. It shall be the duty of the licence holder to secure compliance with—

(a) the conditions of the licence granted by the Authority to the licence holder under paragraph 1 of Schedule 1; and

(b) any requirements imposed by directions given under section 23(1) (conduct of licensed activities) or 24(1) (changes of licence circumstance) of, or paragraph 2(4)(c) to (f) (characteristics of licence) of Schedule 3 to, the 2004 Act, as applied by regulation 6.

Directions

11.—(1) The Authority shall give directions to a licence holder under section 23(1) (conduct of licensed activities) of the 2004 Act, as applied by regulation 6, in accordance with Schedule 2.

(2) The Authority shall revise directions given by virtue of paragraph (1) as it considers necessary.

(3) Schedule 2 has effect.

Guidance

12.—(1) The Authority shall publish such guidance to licence holders as it considers necessary to ensure compliance with **[**F16these Regulations, as they apply in relation to Great Britain, and with the Directive and the Implementing Directive, as they apply in relation to Northern Ireland**]** .

(2) The Authority shall keep the guidance published under paragraph (1) under review and prepare revised guidance when it considers it necessary to do so.

(3) The Authority shall publish the guidance under this regulation in such a way as, in its opinion, is likely to bring it to the attention of licence holders.

F16 Words in reg. 12(1) substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(6)** (as substituted by S.I. 2020/1305, regs. 1, **7**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 4

Other obligations of the Authority

Framework and compliance with licensing conditions and directions

13.—(1) The Authority shall establish and keep updated a framework which shall specify how their requirements for the quality and safety of organs for transplantation shall be met **F17**....

(2) The framework shall cover all stages of the chain from donation to transplantation or disposal and shall include information about the—

(a) procurement activities and transplantation activities that are required to be carried on under the authority of a licence under Schedule 1;

(b) licensing application process;

(c) requirements that licensees must comply with, including the licensing conditions and any directions that the Authority has given under section 23(1) (conduct of licensed activities) of, or paragraph 2(4)(c) to (f) (characteristics of licence) of Schedule 3 to, the 2004 Act, as applied by regulation 6; and

(d) guidance that the Authority has given under regulation 12.

(3) The Authority shall ensure that licence holders are audited for the purposes of ensuring compliance with—

(a) the licensing conditions in Schedule 1; and

(b) any requirements imposed by directions given under section 23(1) or 24(1) (change of licence circumstance) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 6;

at such intervals that the Authority considers appropriate to ensure compliance with such licensing conditions and directions.

F17 Words in reg. 13(1) omitted (31.12.2020) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(7)**; 2020 c. 1, Sch. 5 para. 1(1)

Records and reports

14. The Authority shall—

(a) keep a record of—

(i) the aggregate number of living and deceased donors, and

(ii) the types and quantities of organs procured and transplanted, or otherwise disposed of;

(b) publish an annual report on the activities referred to in paragraph (a); and

(c) establish and keep updated a record of licence holders.

Living donors

15.—(1) The Authority shall keep a record of living donors for the purposes of ensuring the follow-up of living donors.

(2) In cases where a person licensed to carry out the procurement activity of retrieving an organ ceases to be licensed by the Authority, the Authority shall make arrangements which—

(a) ensure that reasonable endeavours are made to follow-up all relevant donors for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation; and

(b) identify and manage any event or reaction identified under sub-paragraph (a).

(3) In paragraph (2), a relevant donor means a living donor from whom the person who has ceased to be licensed retrieved an organ.

Serious adverse events and serious adverse reactions

16.—(1) When a licence holder reports a serious adverse event or a serious adverse reaction to the Authority, or the Authority is otherwise made aware of such an event or reaction, the Authority shall—

(a) rapidly notify that information to **[**F18the**]** persons that the Authority considers may be affected by that information;

(b) investigate the matter where the Authority considers that an investigation will promote the quality and safety of organs; and

(c) register that information.

(2) In carrying out its duties under paragraph (1), the Authority shall ensure the interconnection with the reporting systems established under regulation 20 (duties of the Authority in relation to serious adverse events and serious adverse reactions) of the 2007 Regulations.

F18 Word in reg. 16(1)(a) substituted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **7**

Traceability

17.—(1) The Authority shall ensure that a traceability system is established for the purposes of ensuring notification of serious adverse events or reactions in accordance with regulation 16(1)(a).

(2) Where any person who is licensed to carry out a procurement activity or a transplantation activity ceases to be licensed, the Authority shall make arrangements to ensure that the data collected by that person under the licensing condition in paragraph 2(d) of Schedule 1 is kept for 30 years from the date of the retrieval of the organ.

Organs sent to [F19or received from] another country

[F20**18.**—(1) Where an organ is sent to a Member State from Northern Ireland, the Authority shall ensure that—

(a) information on organ and donor characterisation that is specified in Part A of the Annex to the Directive;

(b) information that has been collected by a registered medical practitioner or a person acting under their supervision that is required by Part B of the Annex at the time when the organ is sent to a Member State; and

(c) information to ensure the traceability of the organ,

is transmitted to that Member State in conformity with the requirements of Articles 4, 5, and 6(1) of the Implementing Directive.

(2) Where an organ is received in Northern Ireland from a Member State, the Authority shall ensure that—

(a) the requirements of Article 4 of the Implementing Directive in relation to information transmitted to the Authority in accordance with that Directive in respect of the organ have been complied with; and

(b) information to ensure the traceability of the organ is transmitted in accordance with Article 6(2) of that Directive.

(3) Where an organ is sent from Northern Ireland to, or received in Northern Ireland from, a Member State, the Authority shall ensure the reporting of serious adverse events and reactions in conformity with the requirements of Articles 4 and 7 of the Implementing Directive.

(4) The Authority shall ensure that any organs sent from Northern Ireland to, or received in Northern Ireland from, countries which are not in the European Union—

(a) can be traced from the donor to the recipient; and

(b) meet quality and safety standards that are equivalent to those required by these Regulations.

(5) The Authority shall ensure that any organs sent from Great Britain to, or received in Great Britain from, countries outside the United Kingdom—

(a) can be traced from the donor to the recipient; and

(b) meet quality and safety standards that are equivalent to those required by these Regulations.

(6) For the purposes of paragraphs (4) and (5), the Authority may conclude agreements with countries outside the United Kingdom.**]**

F19 Words in reg. 18 title inserted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **8(a)**

F20 Reg. 18 substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(8)** (as substituted by S.I. 2020/1305, regs. 1, **8**); 2020 c. 1, **Sch. 5 para. 1(1)**

European Union network of competent authorities

19. The Authority shall, **[**F21in relation to Northern Ireland,**]** whenever reasonably practicable—

(a) participate in the network of competent authorities established by the European Commission; and

(b) co-ordinate United Kingdom input into the activities of that network.

F21 Words in reg. 19 inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(9)** (as substituted by S.I. 2020/1305, regs. 1, **9**); 2020 c. 1, **Sch. 5 para. 1(1)**

Requirement for the Authority to provide information

20.—(1) The Secretary of State may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales and Northern Ireland.

(2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide within a specified period any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland.

(3) The Authority shall, upon receipt of a notice under paragraph (1) or (2), provide the information requested within the period specified in the notice.

PART 5

General

Arrangements by the Authority for assistance with functions

21.—(1) Subject to paragraph (5), the Authority may make arrangements with a body in the United Kingdom for that body to assist the Authority in relation to any of its functions under these Regulations.

(2) Assistance under such arrangements may take the form of the carrying out by the body of the Authority's functions.

(3) Before making arrangements under paragraph (1) the Authority must be satisfied that the body it is proposing to make arrangements with is a suitable body, as defined in paragraph (4).

(4) A suitable body is a body that the Authority determines will carry out functions effectively, efficiently and economically.

(5) Arrangements under paragraph (1) shall not affect the Authority's responsibility for the carrying out of its functions.

(6) The Authority may not make arrangements under paragraph (1) in respect of the giving of—

(a) directions under section 23(1) (conduct of licensed activities) or 24(1) (changes of licence circumstance) of, or paragraph 2(4)(c) to (f) (characteristics of licence) of Schedule 3 to, the 2004 Act; or

(b) regulations under section 21(5) (procedure on reconsideration) of, or paragraphs 10(5) (procedure in relation to licensing decisions) or 13(1) (applications under Schedule 3 to the 2004 Act) of Schedule 3 to, the 2004 Act,

as applied by regulation 6.

Offences by bodies corporate

22.—(1) Where an offence under regulation 8 is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of—

(a) any director, manager, secretary or other similar officer of the body corporate; or

(b) any person who was purporting to act in any such capacity,

that person (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with that member's functions of management as if that member were a director of the body corporate.

(3) Where an offence under this Act is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, that partner (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly.

(4) In subsection (3), partner includes a person purporting to act as a partner.

Licences: transitional arrangements

23.—(1) The requirement to be licensed by the Authority does not apply to a procurement activity or a transplantation activity carried out in respect of an organ that is retrieved from a donor before 27th August 2012.

(2) Where the surgical act of retrieving an organ from the donor commences before 27th August 2012 but is not completed by 27th August 2012, the requirement to be licensed does not apply to any procurement activity or transplantation activity carried out in respect of that organ.

(3) Regulation 9 shall not apply where—

(a) the Authority receives an application for a licence under Schedule 1 before 27th August 2012; and

(b) the Authority is of the opinion that the requirements for that licence are or will be met.

(4) Except where paragraph (5) applies, the duration of a licence granted by the Authority by virtue of paragraph (3) shall be such period not exceeding 4 months as is specified in the licence.

(5) If the Authority is satisfied that—

(a) an applicant for a licence granted by virtue of paragraph (3) meets the requirements specified in regulation 9(2); and

(b) the requirements of regulation 9(3) are met,

it may remove the restriction as to duration imposed under paragraph (4).

Review

24.—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

F22(2) . . . . . .

(3) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning on 27th August 2012.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

F22 Reg. 24(2) omitted (31.12.2020) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(10)**; 2020 c. 1, Sch. 5 para. 1(1)

[F23PART 5A

Power to amend data sets specified in Schedule 1A in relation to Great Britain

F23 Pt. 5A inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(11)** (as amended by S.I. 2020/1305, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

Power for appropriate authority to amend Schedule 1A in relation to Great Britain

24A.—(1) An appropriate authority in Great Britain may by regulations amend—

(a) the minimum data set specified in Part A of Schedule 1A (organ and donor characterisation) where the appropriate authority considers, on the basis of scientific evidence, that the amendment is justified by a serious risk to human health;

(b) the complementary data set specified in Part B of that Schedule where the appropriate authority considers, on the basis of scientific evidence, that it is appropriate to do so.

(2) In this regulation—

"appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(e) for the whole of Great Britain, the Secretary of State acting with the consent of the Welsh Ministers and the Scottish Ministers.

Scope and nature of powers

24B.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 24A are to be made by statutory instrument.

(2) For regulations made under regulation 24A by the Scottish Ministers see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).

(4) Any power in regulation 24A to make regulations includes power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Scrutiny of regulations

24C.—(1) A statutory instrument containing regulations made by the Secretary of State under regulation 24A is subject to annulment in pursuance of a resolution of either House of Parliament.

(2) Regulations made under regulation 24A by the Scottish Ministers are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010 (instruments subject to the negative procedure)).

(3) A statutory instrument containing regulations made by the Welsh Ministers under regulation 24A is subject to annulment in pursuance of a resolution of the National Assembly for Wales.**]**

PART 6

Amendments to other legislation

Amendment of the 2004 Act

25.—(1) The 2004 Act is amended as follows.

(2) In section 14 [M4] (remit)—

(a) in subsection (1) after paragraph (h) insert—

"(i) the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of human organs, in so far as those activities are

activities to which regulation 5(1) of the 2012 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (h).”; and

(b) after subsection (2A) insert—

“(2B) Expressions used in paragraph (i) of subsection (1) and in the 2012 Regulations have the same meaning in that paragraph as in those Regulations.”.

(3) In section 32 (prohibition of commercial dealings in human material for transplantation), after subsection (3) insert—

“(3A) The Authority may not designate a person under subsection (3) to engage in any activity relating to an organ (within the meaning given by Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation) for use for the purpose of transplantation.”.

(4) In section 41(1) [M5] (interpretation of Part 2), after the definition of “the 2007 Regulations” insert—

““the 2012 Regulations” means the Quality and Safety of Organs Intended for Transplantation Regulations 2012;”.

(5) In section 59(4) (provisions extending to Scotland)—

(a) before paragraph (a) insert—

“(za) section 13,”; and

(b) in paragraph (f), after “and 61,” insert—

“(fa) Schedule 2,”.

(6) In Schedule 2 [M6] (the Human Tissue Authority), at the end of paragraph 1 (membership), insert—

“(3) The Scottish Ministers may nominate a person who is a member of the Authority to make representations about the carrying out of its functions in Scotland.”.

(7) In Schedule 3 [M7] (licences for the purposes of section 16), in paragraph 13 (applications under this Schedule), in sub-paragraph (1), for “and Schedule 1 to the 2007 Regulations” substitute “ , Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations ”.

Marginal Citations

M4 Amended by the Human Fertilisation and Embryology Act 2008 (c.22), **Schedule 7**, paragraph 23 and by S.I. 2007/1523.

M5 Amended by S.I. 2007/1523.

M6 Amended by the Health Act 2009 (c.21), **Schedule 3**, Part 1, paragraph 7.

M7 Amended by S.I. 2007/1523.

Amendment of the 2006 Regulations

26. In the 2006 Regulations—

(a) in regulation 2 (interpretation), in the definition of “organ”—

(i) omit “and vital”,

(ii) for “an important” substitute “ a significant ”, and

(iii) at the end of the definition insert “ , and part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation ”;

(b) in regulation 11 (cases in which restriction on transplants involving a live donor is disapplied), at the end of paragraph (2) insert—

"and where that referral concerns an organ, the referral must state that the registered medical practitioner, or a person acting under the supervision of that registered medical practitioner—

(a) is satisfied that the donor's health and medical history are suitable for the purposes of donation; and

(b) has—

(i) provided the donor with the information the donor requires to understand the consequences of donation, and

(ii) endeavoured to obtain information from the donor that is relevant to transplantation.".

(c) after regulation 11(2) insert—

"(2A) In paragraph (2)(b), in cases where the person giving consent is different from the donor, the references to donor shall be read as if they were a references to the person giving consent.".

Amendment of the Human Tissue Act [F24 2006] (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2004

27. In the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 [M8], in regulation 3 (exceptions from licensing requirement)—

F25(a) . . . . . .

(b) in paragraph (5)(a) omit "and vital" and for "an important" substitute " a significant ".

F24 Word in reg. 27 title substituted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **9(a)**

F25 Reg. 27(a) omitted (14.7.2014) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **9(b)**

Marginal Citations

M8 S.I. 2006/1260, to which there are no relevant amending instruments.

Amendment of the 2007 Regulations

28. In the 2007 Regulations, in regulation 9(1) (extension of other provisions of the 2004 Act to Scotland), before "15(a)" insert " 14 (remit), section ".

Amendment of the 2006 Scotland Regulations

29.—(1) The 2006 Scotland Regulations are amended as follows.

(2) In regulation 2 (cases in which restriction on transplants of organs are disapplied), at the end of paragraph (3) insert—

", and that referral must state that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has—

(a) provided the donor with the information required to understand the consequences of donation; and

(b) endeavoured to obtain information from the donor that is relevant to transplantation.".

(3) In regulation 3 (cases in which restriction on transplants of organs are disapplied), in paragraph (5), at the end of sub-paragraph (a) omit "and" and after that sub-paragraph insert—

"(ab) stated in that referral that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has—

(i) provided the donor, or one or more of the individuals referred to in paragraph (6)(b), with the information required to understand the consequences of donation, and

(ii) endeavoured to obtain from the donor, or one or more of the individuals referred to in paragraph (6)(b), information that is relevant to transplantation; and".

(4) In regulation 5 (cases in which restriction on transplants of organs or tissue are disapplied), in paragraph 7, at the end of sub-paragraph (a) omit "and" and insert after that sub-paragraph—

"(ab) stated in that referral that the medical practitioner is satisfied that the donor's health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner's team, has—

(i) provided the donor, or the person referred to in paragraph (8)(b), with the information required to understand the consequences of donation, and

(ii) endeavoured to obtain from the donor or the person mentioned in paragraph (8)(b) information that is relevant to transplantation; and".

Signed by authority of the Secretary of State for Health.

Anne Milton
Parliamentary Under-Secretary of State,
Department of Health

SCHEDULE 1

Regulation 5

Licences for the purposes of regulation 5

1. The Authority may on application grant a licence for the purposes of regulation 5.

Licensing conditions

2. It shall be a condition of a licence for a procurement activity or a transplantation activity for the licence holder—

(a) to have in place operating procedures for the management of a serious adverse event or a serious adverse reaction;

(b) to rapidly report to the Authority—

(i) relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation, and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities, and

(ii) the management measures taken with regard to such a serious adverse event or reaction;

(c) to ensure that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are—

(i) competent,

(ii) suitably qualified or trained, and

(iii) provided with the training necessary,

to perform their tasks;

(d) to ensure that the data required to ensure the traceability of organs is kept for 30 years from the date of the retrieval of the organ;

(e) to keep information on organ and donor characterisation for a period specified by the Authority in directions given under regulation 11;

(f) to ensure that medical activities are performed under the advice and guidance of a registered medical practitioner; and

(g) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (b) and (d) to (f) shall be complied with.

3. It shall be a condition of a licence for a procurement activity for the licence holder—

(a) to ensure that procurement material and equipment which could affect the quality and safety of an organ are managed in accordance with relevant [F26]..., international and national legislation, standards and guidelines on the sterilisation of medical devices; and

(b) to have in place operating procedures demonstrating how the requirements in sub-paragraph (a) shall be complied with.

F26 Words in Sch. 1 para. 3(a) omitted (31.12.2020) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(12)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

4. It shall be a condition of a licence for the procurement activity of retrieval of an organ for a licence holder to ensure that—

(a) the procurement is carried out only after all of the requirements relating to consent and authorisation have been met; and

(b) endeavours are made to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation, and to identify, report to the Authority, and manage any event or reaction.

5. It shall be a condition of a licence for the procurement activity of donor characterisation, and the procurement or transplantation activity of organ characterisation, for the licence holder to ensure—

(a) that where a donor is deceased, a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain information from relatives of the deceased donor or other persons about the donor and has explained to such persons the importance of swift transmission of that information; and

(b) subject to paragraph 7, that donors and organs are characterised before implantation by—

(i) the collection of information specified in part A of **[**F27Schedule 1A**]**, and

(ii) where considered appropriate by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, the collection of the information specified in part B of **[**F28Schedule 1A**]**.

F27 Words in Sch. 1 para. 5(b)(i) substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(12)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)

F28 Words in Sch. 1 para. 5(b)(ii) substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(12)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

6. It shall be a condition of a licence for the transplantation activity of implantation for the licence holder—

(a) to ensure that, subject to paragraph 7, the following have been verified before proceeding to implant an organ in a recipient—

(i) identification of the donor,

(ii) the collection of information prescribed in paragraph 5(b), and

(iii) compliance with the conditions in paragraph 8 about the preservation and transportation of shipped organs; and

(b) to have in place operating procedures demonstrating how the requirements in sub-paragraph (a) (i) and (ii) shall be complied with.

7. Where any of the information specified in part A of **[**F29Schedule 1A**]** is not available, it shall be a licensing condition for the transplantation activity of implantation for the licence holder to conduct a risk-benefit analysis to determine whether the expected benefits for the recipient of the organ outweigh the risks posed by the lack of any information.

F29 Words in Sch. 1 para. 7 substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(12)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

8. It shall be a condition of a licence for a procurement activity or a transplantation activity that arrangements to transport an organ are made by the licence holder—

(a) to maintain the integrity of the organ during transport and that the transport time is suitable to optimise the quality and safety of the organ;

(b) to ensure that, subject to paragraph 9, the shipping containers used for transporting organs are labelled with the following information—

(i) identification of the licence holder responsible for the retrieval of the organ and the place where the retrieval took place, including an address and telephone number for that place,

(ii) identification of the place that an organ will be implanted in a recipient, including its address and telephone number,

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE", and

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

(c) to ensure that the organs transported are accompanied by a report on the organ and donor characterisation; and

(d) to have in place operating procedures demonstrating how the requirements in sub-paragraphs (a) to (c) shall be complied with.

9. The conditions in paragraph 8(b) do not apply where transportation is carried out in the same establishment.

Fees

10. In determining the amounts of any fees to be charged under paragraph 13 (applications under Schedule 3 to the 2004 Act and accompanying fees) of Schedule 3 to the 2004 Act, as applied by regulation 6, the Authority shall have regard to its costs in connection with the consideration of applications for licences under this Schedule.

[F30SCHEDULE 1A

Regulation 5

Organ and Donor Characterisation

F30 Sch. 1A inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(13)**; 2020 c. 1, Sch. 5 para. 1(1)

PART A

Minimum data set

1. The information to be collected pursuant to paragraph 5(b)(i) of Schedule 1 for organ and donor characterisation is the following (the "minimum data set")—

(a) the establishment where the procurement takes place and other general data;

(b) type of donor;

(c) blood group;

(d) gender;

(e) cause of death;

(f) date of death;

(g) date of birth or estimated age;

(h) weight;

(i) height;

(j) past or present history of IV drug abuse;

(k) past or present history of malignant neoplasia;

(l) present history of other transmissible disease;

(m) HIV, HCV, HBV tests;

(n) basic information to evaluate the function of the donated organ.

PART B

Complementary data set

2. The information to be collected pursuant to paragraph 5(b)(ii) of Schedule 1 for organ and donor characterisation is the following (the "complementary data set")—

General data

(a) (a) Contact details of the procurement organisation and (if different) the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

(b) (b) Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor or organ and the recipient.

Donor medical history

(c) (c) Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

(d) (d) Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of the organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

(e) (e) Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

(f) (f) Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

(g) (g) Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.**]**

SCHEDULE 2

Regulation 11

Directions of the Authority

1. For the purposes of ensuring consistent compliance with the licensing conditions prescribed in Schedule 1 , the Authority shall give directions under section 23(1) (conduct of licensed activities) of the 2004 Act, as applied by regulation 6, specifying—

(a) the serious adverse events or serious adverse reactions that must be notified to the Authority, including the time period for such notification;

(b) the data, or type of data, that must be kept to ensure the traceability of organs;

(c) how long information on organ and donor characterisation must be kept for;

(d) the medical activities, or the types of medical activities, that must be performed under the advice and guidance of a registered medical practitioner;

(e) the [F31]... international and national legislation and standards on the sterilisation of medical devices which shall be complied with (and the guidelines on the sterilisation of medical devices which shall be taken into account) in respect of procurement material and equipment which could affect the quality and safety of an organ, or the health of the donor or recipient; and

(f) the adequate facilities and equipment that should be used for organ and donor characterisation.

F31 Words in Sch. 2 para. 1(e) omitted (31.12.2020) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(14)(a)**; 2020 c. 1, Sch. 5 para. 1(1)

2. For the purpose of ensuring consistent standards in relation to the procurement activity of donor characterisation and the procurement or transplantation activity of organ characterisation, the Authority shall specify in directions given under section 23(1) of the 2004 Act—

(a) the requirements that apply to laboratories carrying out tests for donor and organ characterisation, to ensure that those tests are carried out by laboratories with suitably qualified, trained and competent personnel and with adequate facilities and equipment; and

(b) the appropriate operating procedures that are to be in place to ensure that information on organ and donor characterisation reaches the person who will implant the organ in a recipient before the quality and safety of the organ is compromised.

[[F32]**3.** For the purpose of ensuring compliance with the requirements of Articles 4(1), 4(2), 4(3), 5(2) and 5(3) of the Implementing Directive in relation to Northern Ireland, the Authority shall specify in directions given under section 23(1) of the 2004 Act the requirements relating to the transmission of information that apply to a licence holder when an organ is sent to, or received from, a Member State.**]**

F32 Sch. 2 para. 3 substituted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(14)(b)** (as substituted by S.I. 2020/1305, regs. 1, **11**); 2020 c. 1, **Sch. 5 para. 1(1)** Edit

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2010/53/EC of the European Parliament and of the Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation ("the Directive"). These Regulations impose quality and safety requirements in relation to the procurement and transplantation of organs intended for transplantation.

With the exception of regulation 25(2), (3), (4) and (7) and regulation 29, these regulations extend to the whole of the United Kingdom. Regulation 25(2), (3), (4) and (7) extends to England and Wales and Northern Ireland only and regulation 29 extends to Scotland only.

Regulation 4 appoints the Human Tissue Authority ("the Authority") as the competent authority for the purposes of the Directive.

Regulation 5 requires procurement activities and transplantation activities to be carried out under the authority of a licence granted under Schedule 1. Procurement activities include donor characterisation, organ characterisation, preservation of an organ, making arrangements to transport an organ, and retrieval of an organ. Transplantation activities include donor characterisation, organ characterisation, preservation of an organ, making arrangements to transport an organ and implantation of an organ. Regulation 8 makes it an offence to carry out a procurement activity or a transplantation activity without a licence and provides for maximum penalties. Schedule 1 provides for the grant of a licence and regulation 6 applies a number of provisions of the Human Tissue Act 2004 ("the 2004 Act") to such licences, including the procedures to be followed in respect of an application for a licence and the variation, suspension or revocation of a licence and powers to impose fees.

Regulation 9 imposes preconditions to the grant of a licence, which includes the Authority being satisfied that the applicant meets the relevant licensing conditions set out in Schedule 1.

Regulation 10 imposes a duty on the licence holder to ensure that only suitable persons participate in carrying on the activities, that suitable practices are used in doing so, and that the conditions of the licence and requirements imposed by directions are complied with. Regulation 11 imposes an obligation on the Authority to give directions in accordance with Schedule 2 to ensure consistent compliance by licence holders with the licensing conditions. Regulation 12 imposes an obligation on the Authority to give guidance to licence holders.

Regulation 13 imposes an obligation on the Authority to establish and maintain a Framework which covers all stages of the chain from donation to transplantation and includes information about licensing. It also imposes an obligation on the Authority to ensure that licence holders are controlled for the purposes of ensuring compliance with the Directive. Regulations 14 to 18 impose further obligations on the Authority, including requirements to keep records and publish reports, make arrangements to endeavour to follow up living donors in particular cases, obligations in respect of serious adverse events and reactions, requirements to establish and maintain a traceability system, keep traceability data in particular cases and obligations in respect of organs sent to another country. Regulation 19 requires the Authority to participate in the EU network of competent authorities, and regulation 20 provides that the Authority must

provide information to the Secretary of State or the Scottish Ministers if requested to do so by the Secretary of State or the Scottish Ministers.
Regulation 21 permits the Authority to make arrangements which permit another body to assist the Authority with its functions. Regulation 22 provides that an officer or member of a body corporate, or a partner in Scottish partnership, commits an offence when it is proved that such body or partnership committed an offence under these Regulations with the consent or connivance of that officer or partner, or it was attributable to neglect on the part of that officer, member or partner.
Regulation 23 makes transitional provisions in respect of a procurement activity or a transplantation activity that is commenced before the 27thAugust 2012.
Regulation 24 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come fully into force and within every five years after that. Following a review, it will fall to the Secretary of State to consider whether these Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke these regulations or to amend them.
Regulation 25 makes consequential amendments to the 2004 Act, including an amendment to section 32 of that Act. Section 32 prohibits specified commercial dealings in human material for transplantation, but subsection (3) permits persons to engage in those specified activities if the Authority designates that person lawfully to engage in that activity. Regulation 25 restricts section 32(3) by removing the Authority's power to designate an individual lawfully to carry out those specified activities when they relate to an organ intended to be used for the purposes of transplantation. Regulation 25 also makes an amendment to Schedule 2 to the 2004 Act to permit Scottish Ministers to nominate a member of the Authority to make representations about the carrying out of the Authority's functions in Scotland. Regulation 26 makes amendments to the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 to align the definition of an organ to the definition of an organ in the Directive and these Regulations, and to impose further obligations on a medical practitioner who has referred the matter of removing an organ to the Authority for approval.
Regulation 27 makes an amendment to the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 to align the definition of an organ to the definition of an organ in the Directive and these Regulations, and regulation 28 makes an amendment to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to extend section 14 of the 2004 Act to Scotland so far as it relates to activities within section 14(1)(h) of the 2004 Act. Regulation 29 makes amendments to the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.
An Impact Assessment and a Transposition Note have been prepared for these Regulations. Copies of the Impact Assessment and the Transposition Note can be obtained from the Organ and Tissue Transplantation Team, Department of Health, Area 6.21, 6th floor South, Wellington House, 133-135 Waterloo Road, London SE1 8UG and are published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012.