STATUTORY INSTRUMENTS

2019 No. 483

EXITING THE EUROPEAN UNION
HUMAN TISSUE

The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019

Made - - - - 5th March 2019

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 23(1) of the European Union (Withdrawal) Act 2018 [M1].

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Marginal Citations

M1 2018 c. 16.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

Commencement Information

I1 Reg. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, Sch. 5 para. 1(1)), see reg. 1

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

2.—(1) Section 32 of the Human Tissue Act 2004 [M2] (prohibition of commercial dealings in human material for transplantation) is amended as follows.

[[F1](2) For subsection (3A) substitute—

"(3A) The Authority may not designate a person under subsection (3) if doing so would be incompatible with the principles set out in—

(a) Article 12 of Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or

(b) 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,

and for the purposes of this subsection as it applies in relation to Great Britain, those Articles of those Directives are to be read subject to the modifications set out in subsections (3B) and (3C).".**]**

(3) After subsection (3A) insert—

"(3B) Article 12 of Directive 2004/23/EC[M3] is to be read as if—

(a) in paragraph 1—

(i) for the first subparagraph there were substituted—

"Donations of tissues and cells shall be voluntary and unpaid.";

(ii) in the second subparagraph, the second sentence were omitted;

(iii) the third subparagraph were omitted;

(b) in paragraph 2, for the first subparagraph there were substituted—

"Any promotion and publicity activities in support of the donation of human tissues and cells shall comply with any directions of the Authority or any provision of any enactment which relates to such activities.";

(c) also in paragraph 2, in the second subparagraph—

(i) "Member States shall endeavour to ensure that" were omitted;

(ii) for "is" there were substituted " shall be ".

(3C) Article 13 of Directive 2010/53/EU [M4] is to be read as if—

(a) in paragraph 1—

(i) "Member States shall ensure that" were omitted; and

(ii) for "are" there were substituted " shall be ".

(b) in paragraph 2, the second sentence were omitted;

(c) in paragraph 3—

(i) "Member States shall prohibit" were omitted; and

(ii) at the end there were inserted "shall be prohibited";

(d) in paragraph 4—

(i) "Member States shall ensure that" were omitted; and

(ii) for "is" there were substituted " shall be ".".

Textual Amendments

F1 Reg. 2(2) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **3**

Commencement Information

I2 Reg. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 2004 c. 30. Section 32 was amended by S.I. 2012/1501 and 2014/1459.
M3 OJ No L 102, 07.04.2004, p48.
M4 OJ No L 207, 06.08.2010, p14.

PART 3

Amendment of subordinate legislation

Amendment of the Quality and Safety of Organs Intended for Transplantation Regulations 2012

3.—(1) The Quality and Safety of Organs Intended for Transplantation Regulations 2012 [M5] are amended as follows.

(2) In regulation 3 (interpretation)—

(a) the existing text becomes paragraph (1);

(b) in that paragraph (1)—

[[F2](i) n the definition of "the Directive", at the end insert ", as it applies in relation to Northern Ireland";**]**

[[F3](ii) in the definition of "the Implementing Directive", at the end insert ", as it applies in relation to Northern Ireland";**]**

(iii) after the definition of "procurement activity" insert—

""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;";

(c) after paragraph (1) insert—

"(2) In these Regulations, **[**[F4]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.".

[[F5](3) For regulation 4 (designation of the competent authority) substitute—

"**Designation of the competent authority in relation to Northern Ireland**

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

(4) In regulation 5 (licensing requirement), at the end insert—

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

(5) In regulation 6 [M6] (application of the 2004 Act in relation to licences under Schedule 1), for "the Directive and the Implementing Directive", in each place where those words appear, substitute "**[**[F6]these 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**]**".

(6) In regulation 12 [M7] (guidance), in paragraph (1) for "the Directive and the Implementing Directive" substitute " **[**[F7]these 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**]**".

(7) In regulation 13 [M8] (framework and compliance with licensing conditions and directions), in paragraph (1) omit "in compliance with the Directive and the Implementing Directive".

[[F8](8) For regulation 18 (organs sent to or received from another country), substitute—

"**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.".**]**

[F9(9) In regulation 19 (European Union network of competent authorities), after "The Authority shall," insert "in relation to Northern Ireland,**]**

(10) In regulation 24 (review) omit subsection (2).

(11) After regulation 24 insert—

"PART 5A

Power to amend data sets specified in Schedule 1A **[**F10in relation to Great Britain**]**

Power for appropriate authority to amend Schedule 1A [F11in relation to Great Britain]

24A.—(1) **[**F12An 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;

(d) F13...

(e) **[**F14for 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 M9 (Scottish statutory instruments).

F15(3) . . . . . .

(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.

F16(4) . . . . . ".

(12) In Schedule 1 (licences)—

(a) in paragraph 3(a) omit "European Union,";

(b) in paragraph 5(b)—

(i) in paragraph (i), for "the Annex to the Directive" substitute " Schedule 1A ";

(ii) in paragraph (ii), for the words from "the Annex" to the end substitute " Schedule 1A ";

(c) in paragraph 7 for "the Annex to the Directive" substitute " Schedule 1A ".

(13) After Schedule 1 insert—

"SCHEDULE 1A Regulation 5

Organ and Donor Characterisation

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

Donor medical history

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

Therapy

(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.".

(14) In Schedule 2 (directions of the Authority)—

(a) in paragraph 1, in sub-paragraph (e) omit "European Union,";

[[F17](b) for paragraph 3 substitute—

"**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.".**]**

Textual Amendments

F2 Reg. 3(2)(b)(i) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **4(a)**

F3 Reg. 3(2)(b)(ii) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **4(b)**

F4 Words in reg. 3(2)(c) inserted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **4(c)**

F5 Reg. 3(3) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **5**

F6 Words in reg. 3(5) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **6**

F7 Words in reg. 3(6) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **7**

F8 Reg. 3(8) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **8**

F9 Reg. 3(9) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **9**

F10 Words in reg. 3(11) inserted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(a)**

F11 Words in reg. 3(11) inserted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(b)**

F12 Words in reg. 3(11) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(c)**

F13 Words in reg. 3(11) omitted (31.12.2020 immediately before IP completion day) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(d)(i)**

F14 Words in reg. 3(11) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(d)(ii)**

F15 Words in reg. 3(11) omitted (31.12.2020 immediately before IP completion day) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(e)**

F16 Words in reg. 3(11) omitted (31.12.2020 immediately before IP completion day) by virtue of The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **10(f)**

F17 Reg. 3(14)(b) substituted (31.12.2020 immediately before IP completion day) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1305), regs. 1, **11**

Commencement Information

I3 Reg. 3 in force at 31.12.2020 in force on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M5 S.I. 2012/1501, amended by S.I. 2014/1459 and 2015/1679.

M6 Regulation 6 was amended by S.I. 2014/1459.

M7 Regulation 12 was amended by S.I. 2014/1459.

M8 Regulation 13 was amended by S.I. 2014/1459.

M9 2010 asp 10.

Signed by authority of the Secretary of State for Health and Social Care.

Jackie Doyle-Price
Parliamentary Under-Secretary of State,
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 23(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (f) and (g)) arising from the withdrawal of the UK from the European Union.

These Regulations make amendments to legislation in the field of procedures to be followed and information to be transmitted in connection with ensuring the quality and safety of organs intended for transplantation.

Part 2 amends primary legislation. Part 3 amends subordinate legislation, including to confer a power for the appropriate authority to make regulations in connection with the information to be collected concerning the characterisation of organs and donors.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

Changes to legislation:
There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019.