DRAFT STATUTORY INSTRUMENTS

2019 No.

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

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(**1**) are amended as follows.

(2) In regulation 3 (interpretation)—

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

(b) in that paragraph (1)—

(i) omit the definition of "the Directive";

(ii) omit the definition of "the Implementing Directive"(**2**);

(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, 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.".

(3) Omit regulation 4 (designation of the competent authority).

(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(**3**) (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 "these Regulations".

(**1**) S.I. 2012/1501, amended by S.I. 2014/1459 and 2015/1679.
(**2**) The definition of "the Implementing Directive" was inserted by S.I. 2014/1459.
(**3**) Regulation 6 was amended by S.I. 2014/1459.

(6) In regulation 12(**4**) (guidance), in paragraph (1) for "the Directive and the Implementing Directive" substitute "these Regulations".

(7) In regulation 13(**5**) (framework and compliance with licensing conditions and directions), in paragraph (1) omit "in compliance with the Directive and the Implementing Directive".

(8) In regulation 18(**6**) (organs sent to or received from another country)—

(a) omit paragraphs (1), (1A) and (2);

(b) in paragraph (3) for "to, or received from, countries which are not in the European Union" substitute ", or received from, outside the United Kingdom";

(c) in paragraph (4) for "that are not in the European Union" substitute "outside the United Kingdom".

(9) Omit regulation 19 (European Union network of competent authorities).

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

(11) After regulation 24 insert—

"PART 5A

Power to amend data sets specified in Schedule 1A

Power for appropriate authority to amend Schedule 1A

24A.—(1) The appropriate authority 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) in relation to Northern Ireland—

(i) the Department of Health in Northern Ireland; or

(ii) the Secretary of State acting with the consent of that Department;

(e) for the whole of the United Kingdom, the Secretary of State acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department for Health in Northern Ireland.

(**4**) Regulation 12 was amended by S.I. 2014/1459.
(**5**) Regulation 13 was amended by S.I. 2014/1459.
(**6**) Regulation 18 was amended by S.I. 2014/1459.

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(**7**) (Scottish statutory instruments).

(3) Any power of the Department of Health in Northern Ireland to make regulations under regulation 24A is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**8**).

(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.

(4) Regulations made by the Department of Health in Northern Ireland under regulation 24A are subject to negative resolution within the meaning of section 41(6) of the Interpretation Act (Northern Ireland) 1954(**9**) (definitions for parliamentary purposes) as if they were a statutory instrument within the meaning of that Act.".

(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—

(**7**) 2010 asp 10.
(**8**) S.I. 1979/1573 (N.I. 12).
(**9**) 1954 c. 33.

"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,";

(b) omit paragraph 3(**10**).

(**10**) Paragraph 3 was inserted by S.I. 2014/1459.