STATUTORY INSTRUMENTS

2012 No. 1501

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

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 in compliance with the Directive.

(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.

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 such 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.

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 another country

18.—(1) Where an organ is sent to another country in the European Union, 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 another country in the European Union; and

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

is transmitted to that country in conformity with any procedures established by the Commission under article 29 of the Directive.

(2) Where an organ is sent to, or received from, a country in the European Union, the Authority shall ensure the reporting of serious adverse events and reactions in conformity with any procedures established by the Commission under article 29 of the Directive.

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

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

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

(4) For the purposes of paragraph (3), the Authority may conclude agreements with countries that are not in the European Union.

European Union network of competent authorities

19. The Authority shall, 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.

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.