STATUTORY INSTRUMENTS

2012 No. 1501

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

PART 4

Other obligations of the Authority

Organs sent to [F1or received from] another country

[F2 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.**]**

Textual Amendments

F1 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)**

F2 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)**

Changes to legislation:
There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Section 18.