DRAFT STATUTORY INSTRUMENTS

2018 No.

The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018

Amendment of Part 4 of the Principal Regulations

5.—(1) In regulation 20(1)(a) of the Principal Regulations (duties of the Authority in relation to serious adverse events and serious adverse reactions), for "import or export", substitute "import into the United Kingdom from a third country or export from the United Kingdom to a third country".

(2) After regulation 20 of the Principal Regulations, insert—

"**20A. Duties of the Authority in relation to application of the Single European Code**

(1) The Authority must allocate to each licence holder one or more unique numbers to be the tissue establishment number or numbers in relation to that licence holder in accordance with Annex VII and paragraph 2(a) of Article 10b of the third Directive.

(2) Any number allocated under paragraph (1) must be in the format specified in Annex VII to the third Directive.

(3) The Authority must, in relation to each licence holder, arrange for the information specified in Annex VIII to the third Directive to be recorded in the EU Tissue Establishment Compendium.

(4) In relation to a licence holder, the Authority must ensure that the information under paragraph (3) is recorded before the end of the period of 10 working days beginning with 1st April 2018.

(5) In relation to a person who becomes a licence holder on or after 1st April 2018 the Authority must ensure that the information under paragraph (3) is recorded before the end of the period of 10 working days beginning with the day on which the person becomes a licence holder.

(6) Paragraph (7) applies if the Authority becomes aware that any information recorded under paragraph (3) was incorrectly recorded or requires updating.

(7) Where this paragraph applies, the Authority must arrange for the information to be corrected or updated—

(a) in the case of a correction or update that the Authority considers to be a significant change to the information recorded under paragraph (3), before the end of the period of 10 working days beginning with the day on which the Authority became aware that the information was incorrectly recorded or required updating;

(b) in any other case, as soon as is reasonably practicable.

(8) Paragraph (9) applies if the Authority becomes aware that—

(a) any information recorded in the EU Tissue Establishment Compendium in respect of a tissue establishment in a relevant state was incorrectly recorded or requires updating; or

(b) a tissue establishment in a relevant state has not complied with the requirements of the laws or other measures adopted in that state for the purpose of implementing paragraph 1 of Article 10b of the third Directive and the non-compliance is significant.

(9) Where this paragraph applies, the Authority must inform the competent authority in the relevant state in question of the information to be corrected or updated or the non-compliance in question.

(10) If the Authority becomes aware that the information recorded in the EU Tissue and Cell Product Compendium requires updating, it must inform the European Commission and the competent authority in the relevant state.

(11) In this regulation—

"relevant state" means—

(a) an EEA state other than the United Kingdom; or

(b) Gibraltar; and

"working day" means any day other than—

(a) a Saturday or Sunday;

(b) Christmas Day or Good Friday; or

(c) a day which is a bank holiday under the Banking and Financial Dealings Act 1971(**1**) in any part of the United Kingdom.

20B. Inspection of third country premises etc

(1) Paragraph (2) applies where—

(a) qualifying tissues or cells are imported into the United Kingdom from a third country by an importing licence holder;

(b) the tissues or cells are distributed in an EEA state, other than the United Kingdom, or in Gibraltar; and

(c) the competent authority in that state or in Gibraltar ("the requesting authority") requests the Authority to carry out any of the following activities—

(i) to arrange for an inspection of any third country premises to be carried out on behalf of the Authority;

(ii) to arrange for an inspection of any relevant documents held by a third country supplier to be carried out on behalf of the Authority;

(iii) to exercise the Authority's power under paragraph 7(2) of Schedule 3 to the 2004 Act to revoke a licence held by an importing licence holder;

(iv) to exercise the Authority's powers under paragraph 8(3) of Schedule 3 to the 2004 Act to vary a licence held by an importing licence holder; or

(v) other appropriate control measures.

(2) The Authority must carry out the activity in question specified in paragraph (1)(c), unless it considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Before an inspection of any premises is carried out pursuant to paragraph (2), the Authority must—

(**1**) 1971 c.80 (section 1(1) and Schedule 1).

(a) make arrangements with the competent authority which made the request under paragraph (1) for that competent authority to participate in the inspection; or

(b) notify the competent authority which made the request under paragraph (1) that the Authority has decided that it is not appropriate for that competent authority to participate in the inspection and give reasons for that decision.

(4) For the purposes of ascertaining whether qualifying tissues or cells imported into the United Kingdom from a third country meet standards of quality and safety equivalent to those laid down in these Regulations, the Authority may arrange for either or both of the following to be carried out on its behalf—

(a) an inspection of any third country premises; or

(b) an inspection of any relevant document held by a third country supplier.

(5) The Authority may arrange for a report to be made on any inspection carried out in pursuance of paragraph (2) or (4).

(6) Any inspection carried out in pursuance of paragraphs (2) and (4) must be carried out by a person authorised by the Authority for the purposes of this regulation.

(7) An inspection of any premises made under this regulation must include, in particular—

(a) the inspection of any equipment found on the premises;

(b) the inspection and copying of any relevant documents or records found on the premises; and

(c) the observation of any activity relevant to ascertaining whether qualifying tissues or cells imported from a third country meet standards of quality and safety equivalent to those laid down in these Regulations.

(8) In this regulation—

"qualifying tissues or cells" means tissues or cells intended for human application;

"relevant documents" mean documents relevant for the purposes of ascertaining whether qualifying tissues or cells imported from a third country meet standards of quality and safety equivalent to those laid down in these Regulations;

"requesting authority" has the meaning given in paragraph (1)(c).

20C. Third country premises and third country suppliers: report of inspections etc

(1) This regulation applies where the European Commission or a competent authority in an EEA state, other than the United Kingdom, or in Gibraltar requests the Authority to provide it with—

(a) a copy of a report or information on any inspection of third country premises or relevant documents carried out in pursuance of regulation 20B(2) or (4);

(b) information on any exercise of the Authority's powers under paragraph 7(2), 8(3) or 9(1) of Schedule 3 to the 2004 Act (licences for the purposes of section 16) in relation to a licence held by an importing licence holder (whether in pursuance of regulation 20B(2) or otherwise); or

(c) information on any appropriate control measures (whether in pursuance of regulation 20B(2) or otherwise).

(2) The Authority must provide the report or information in question to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.".