STATUTORY INSTRUMENTS

2020 No. 1306

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020

Amendment of regulation 3(21)

25. In regulation 3(21)—

(a) in sub-paragraph (a), in paragraph 1 as substituted by that provision, for "Directions" substitute "In relation to Great Britain, directions";

(b) after sub-paragraph (a) insert—

"(aa) after paragraph 1 insert—

"**1ZA.** In relation to Northern Ireland, directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and

(b) in relation to the coding of information, compliance with—

(i) the requirements of paragraph 1 of Article 25 of the first Directive (coding of information);

(ii) the requirements of paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article;

(iii) the requirements of Article 10a of the third Directive (format of the Single European Code); and

(iv) the requirements of paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).";";

(c) for sub-paragraph (b) substitute—

"(b) in paragraph 1A, for "Directions" substitute "In relation to Northern Ireland, directions";";

(d) for sub-paragraph (c) substitute—

"(c) in paragraph 4—

(i) for "Directions shall" substitute "In relation to Great Britain, directions shall";

(ii) for the words from "are necessary" to the end substitute "as the Authority considers appropriate;";

(e) after sub-paragraph (c) insert—

"(ca) after paragraph 4 insert—

"**4ZA.** In relation to Northern Ireland, directions shall require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.";";

(f) for paragraph (d) substitute—

"(d) in paragraph 7—

(i) in the words before sub-paragraph (a), for "Directions shall" substitute "In relation to Great Britain, directions shall";

(ii) in sub-paragraph (b), for "the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive" substitute "the requirements of these Regulations in relation to notification of serious adverse reactions and notification of serious adverse events.";";

(g) after paragraph (d) insert—

"(e) after paragraph 7 insert—

"**7A.** In relation to Northern Ireland, directions shall be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.";

(f) in paragraph 15(5), in the definition of "qualifying import", omit "into the United Kingdom".".