STATUTORY INSTRUMENTS

2020 No. 1307

The Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020

Amendment of regulation 2(17)

16. In regulation 2(17)—

(a) in the new paragraph A1 inserted by sub-paragraph (a), after "this Act," insert "as it applies in relation to Great Britain,";

(b) for sub-paragraph (b) substitute—

"(b) in paragraph 3—

(i) in the heading, at the end insert ": Great Britain";

(ii) for "Licence" substitute "In relation to Great Britain, licence";

(iii) in the words following sub-paragraph (b), for the words from "are necessary" to the end substitute "the Authority considers appropriate";

(ba) after paragraph 3 insert—

"**Serious adverse events and serious adverse reactions: Northern Ireland**

3A. In relation to Northern Ireland, licence conditions shall require 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,

to be in place 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.".";

(c) in the new paragraph 11A inserted by sub-paragraph (c), in sub-paragraph (2)(a)(ii) for "in the United Kingdom" substitute "in Great Britain".