

**Changes to legislation:** There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Cross Heading: Serious adverse events and serious adverse reactions : Great Britain. (See end of Document for details)

## SCHEDULES

### [<sup>F1</sup>SCHEDULE 3A

#### SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

##### Textual Amendments

- F1** Sch. 3A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs 1, **30**

*Serious adverse events and serious adverse reactions [<sup>F2</sup>: Great Britain]*

##### Textual Amendments

- F2** Words in Sch. 3A para. 3 heading inserted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(17)(b)(i)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **16(b)**)

- 3 [<sup>F3</sup>In relation to Great Britain, 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 [<sup>F4</sup>the Authority considers appropriate].]

##### Textual Amendments

- F3** Words in Sch. 3A para. 3 substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(17)(b)(ii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **16(b)**)
- F4** Words in Sch. 3A para. 3 substituted (31.12.2020) by [S.I. 2019/482](#), **reg. 2(17)(b)(iii)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **16(b)**)

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