

SCHEDULES

[^{F1}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**

[^{F2}Serious adverse events and serious adverse reactions: Northern Ireland

Textual Amendments

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

- 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.]]

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: Northern Ireland.