SCHEDULES

[F1SCHEDULE 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**

[F2Serious 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.