DRAFT STATUTORY INSTRUMENTS

2019 No.

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 12

Amendment of Part 12 (dealings with medicinal products)

Amendment of regulation 254 (prohibitions concerning traceability of treatment with advanced therapy medicinal products)

195. In regulation 254(2)(a), for the words from "laid down in" to the end, substitute—

"imposed pursuant to—

(a) as regards gametes and embryos, sections 12(3), and 33A to 33D of, and paragraph 1 of Schedule 3A to, the Human Fertilisation and Embryology Act 1990(**1**);

(b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005(**2**); and

(c) as regards other cells and tissues, regulations 13 and 16 of, and paragraph 1 of Schedule 2 to, the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**3**);".

(**1**) 1990 c. 37. Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.
(**2**) S.I. 2005/50. It has been amended by S.I. 2005/1098 and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/604, 2017/1320 and 2018/231.
(**3**) S.I. 2007/1523.