
STATUTORY INSTRUMENTS

2019 No. 775

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

PART 3

**Amendment of Part 3 (manufacture and distribution
of medicinal products and active substances)**

**Amendment of Schedule 6 (manufacturer's and wholesale dealer's licences for exempt
advanced therapy medicinal products)**

26.—(1) Schedule 6 is amended as follows.

(2) In paragraph 3, for “Directive [2004/23/EC](#)”, substitute—

“requirements imposed pursuant to—

- (a) paragraphs 6 to 9 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and
- (b) paragraphs 9 to 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.”.

(3) In paragraph 4, for the words “laid down in” to the end, substitute—

“imposed pursuant to—

- (a) Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards gametes and embryos; and
- (b) Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other tissues and cells.”.

(4) In paragraph 5, for the words from “Commission” to the end substitute “ the Blood Quality and Safety Regulations 2005 ^{M1} ”.

(5) In paragraph 11, 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 ^{M2};
- (b) as regards blood cells, regulations 8, 9(e) and 14 of the Blood Safety and Quality Regulations 2005; 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;”.

Changes to legislation: There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 26. (See end of Document for details)

Commencement Information

- I1** Reg. 26 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)), see [reg. 1](#)
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Marginal Citations

- M1** [S.I. 2005/50](#). It was amended by [S.I. 2005/1098](#) and 2898, 2006/2013, 2007/604, 2008/525 and 941, 2009/372 and 3307, 2010/554, 2016/604, 2017/1320 and 2018/231.
- M2** Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 26.