DRAFT STATUTORY INSTRUMENTS

2019 No.

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(**1**)".

(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(**2**);

(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;".

(**1**) 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.

(**2**) Sections 33A to 33D were inserted by the Human Fertilisation and Embryology Act 2008, c. 22.