DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of Schedule 8 (material to accompany an application for a UK marketing authorisation)

50.—(1) Schedule 8(**1**) is amended as follows.

(2) In paragraph 12—

(a) in sub-paragraph (a), after "pharmacovigilance" insert "who is ordinarily resident, and operates, in the United Kingdom";

(b) omit sub-paragraph (b); and

(c) in paragraph (e) at the end insert "or, if kept in electronic form, from which it can be accessed, which in either case, must be in the United Kingdom".

(3) For paragraph 18 substitute—

"**18.** Where an application for authorisation for the medicinal product to be placed on the market is under consideration in a country other than the United Kingdom, or by the EMA, notification of that fact.".

(4) In paragraph 19, for "a member state or by a third country", substitute "a country other than the United Kingdom or by the European Commission".

(5) Omit paragraph 20.

(6) In paragraph 21, for "a member state or by a third country", substitute "a country other than the United Kingdom".

(7) Omit paragraph 22.

(8) In paragraph 23—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

(9) After paragraph 25, insert—

"**25A.** In the case of an advanced therapy medicinal product which contains cells or tissues, a detailed description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.".

(10) After paragraph 35, insert—

(**1**) Schedule 8 was amended by S.I. 2013/1855.

"**36.** In the case of an advanced therapy medicinal product—

(a) references in this Part of this Schedule to administration of a product include references to the advanced therapy medicinal product's use, application or implantation; and

(b) descriptions, instructions and warnings must include explanatory drawings and pictures where necessary.".