DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 5

Amendment of Part 5 (marketing authorisations)

Post authorisation requirements in relation to UK marketing authorisations with paediatric aspects and advanced therapy medicinal products

87. After regulation 78, insert—

"**Post authorisation requirements in relation to UK marketing authorisations to which paediatric specific provisions apply**

78A.—(1) Paragraph (2) applies where—

(a) a holder of a UK marketing authorisation intends to discontinue supply of the product to which that authorisation relates;

(b) the holder of the authorisation benefited from a reward or incentive under regulation 58A(3) or (8) or 58D(5) in relation to the product; and

(c) the period of protection provided pursuant to those regulations has expired.

(2) Where this paragraph applies, the holder of the UK marketing authorisation must—

(a) either—

(i) transfer the UK marketing authorisation to another person who has declared an intention to continue to supply the product; or

(ii) allow such a person to use the pharmaceutical, pre-clinical and clinical documentation contained in the file on that product in accordance with regulation 56; and

(b) notify the licensing authority of its intention to cease to supply the product before the beginning of the period of six months ending immediately before the day on which the holder does so.

(3) Paragraph (4) applies to the holder of a UK marketing authorisation if—

(a) that authorisation includes a paediatric indication following completion of an agreed paediatric investigation plan; and

(b) the product was placed on the market for other indications before that holder obtained that paediatric indication.

(4) Where this paragraph applies, the holder of the UK marketing authorisation must place the product on the market taking account of the paediatric indication before the end of the period of two years beginning immediately after the day on which the paediatric indication is authorised.

(5) Paragraph (6) applies if—

(a) a decision by the licensing authority in respect of a paediatric investigation plan is addressed to a person ("PIP sponsor"); and

(b) the plan refers to clinical trials carried out in a country other than the United Kingdom ("non-UK clinical trials").

(6) Where this paragraph applies, the PIP sponsor must send to the licensing authority the details set out in Article 11 of the Clinical Trials Directive in relation to the non-UK clinical trials within whichever is the later of—

(a) the period of one month beginning after the day on which the decision was received; or

(b) the period of one month beginning after the day on which the necessary permission to conduct the clinical trial was received from the competent authorities in the country where the clinical trial is to take place.

(7) Where paragraph (6) applies, the PIP sponsor must submit the results of those clinical trials to the licensing authority within the period of twelve months beginning with the day on which the last of those trials ended, subject to paragraph (8).

(8) Paragraph (7) does not apply in the case of a clinical trial which forms part of a paediatric study to which paragraph (12) applies.

(9) Paragraph (10) applies in relation to the sponsor of a paediatric clinical trial in the United Kingdom in respect of a medicinal product if—

(a) the product has a UK marketing authorisation but the sponsor is not the holder of the authorisation; or

(b) the product does not have a UK marketing authorisation.

(10) Where this paragraph applies, the sponsor of the clinical trial must submit the results of the trial to the licensing authority within the period of twelve months beginning with the day on which the trial ended.

(11) Paragraph (12) applies in relation to the holder of a UK marketing authorisation who sponsors a paediatric clinical trial in respect of the medicinal product to which that authorisation relates.

(12) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the trial to the licensing authority within the period of six months beginning with the day on which the trial ended.

(13) Paragraph (14) applies in relation to the holder of a UK marketing authorisation who sponsors a study which involves the use in the paediatric population of a medicinal product to which that UK marketing authorisation relates, irrespective of whether or not—

(a) the studies are conducted in accordance with an agreed paediatric investigation plan; or

(b) the marketing authorisation holder intends to apply for a marketing authorisation for a paediatric indication in relation to the product.

(14) Where this paragraph applies, the holder of the UK marketing authorisation must submit the results of the study to the licensing authority within the period of six months beginning with the day on which the study ended.

(15) Where the licensing authority has granted a deferral of the initiation or completion of some or all of the measures set out in a paediatric investigation plan, in accordance with regulation 50C, the person to whom that decision was addressed must submit to the licensing authority an annual report providing an update on progress with the paediatric studies to which the deferral relates.

(16) The first report referred to in paragraph (15) must be submitted within the period of twelve months beginning with the date on which the licensing authority granted the deferral.

Post authorisation requirements in relation to UK marketing authorisations for advanced therapy medicinal products

78B.—(1) The holder of a UK marketing authorisation in respect of an advanced therapy medicinal product must—

(a) establish and maintain a system ensuring that the individual product and its starting raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private practice where the product is used;

(b) where the product contains human tissues or cells, ensure that the traceability system is complementary to and compatible with requirements imposed pursuant to—

(i) 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**),

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

(iii) 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**);

(c) keep the data referred to in paragraph (a) for a minimum of 30 years after the expiry of the date of the product, or longer if required by the licensing authority as a term of the UK marketing authorisation; and

(d) in the event of the UK marketing authorisation holder's bankruptcy or liquidation occurring within the period of time for which that holder is required to keep the data referred to in paragraph (a), transfer that data to another person or the licensing authority.

(2) The holder of a UK marketing authorisation who is subject to the obligations in paragraph (1) remains subject to them even if the UK marketing authorisation is suspended or revoked.".

(**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 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.
(**3**) S.I. 2007/1523.