DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 52 (applications relating to certain medicinal products that do not qualify as generic etc)

57.—(1) Regulation 52 is amended as follows.

(2) In paragraph (1)(a), for "as reference medicinal product" substitute—

"which is or has been authorised for not less than eight years—

(i) under regulation 49(1)(a) (subject to paragraphs (2) and (3) of regulation 51), or

(ii) if the reference medicinal product is an EU reference medicinal product, under Regulation (EC) No 726/2004; and".

(3) For paragraph (1)(b) substitute—

"(b) one or more of the following circumstances applies in respect of the application—

(i) the medicinal product to which the application relates does not fall within the definition of generic medicinal product,

(ii) bioequivalence with the reference medicinal product cannot be demonstrated through bioavailability studies, or

(iii) the medicinal product to which the application relates differs from the reference medicinal product in terms of changes in the active substance, therapeutic indications, strength, pharmaceutical form or route of administration.".

(4) For paragraph (2), substitute—

"(2) The applicant—

(a) may, by way of derogation from paragraph 10 of Schedule 8, omit from the application the results of pre-clinical tests and of clinical trials relating to the reference medicinal product; but

(b) must provide the results of the appropriate pre-clinical tests or clinical trials relating to the applicable circumstance in paragraph (1)(b).".

(5) In paragraph (3)—

(a) for "Regulation 51(2)" substitute "Paragraphs (2) to (14) of regulation 51"; and

(b) for "it applies" substitute "they apply".