STATUTORY INSTRUMENTS

2019 No. 775

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

PART 5

Amendment of Part 5 (marketing authorisations)

Amendment of regulation 53 (applications relating to similar biological medicinal products)

58.—(1) Regulation 53 is amended as follows.

(2) In paragraph (1), for the words from "any of the reasons" to the end, substitute "differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product."

(3) 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 appropriate pre-clinical tests or clinical trials relating to the differences referred to in paragraph (1).

(2A) The type and quantity of supplementary data to be provided by the applicant under paragraph (2)(b) must comply with the relevant criteria in Annex I to the 2001 Directive and in the related detailed guidelines published by the licensing authority under paragraph (2B), or (as the case may be) as mentioned in paragraph (2C).

(2B) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (2)(b).

(2C) Unless replaced by guidelines published under paragraph (2B), the guidelines published by the EMA under Article 10(4) of the 2001 Directive(**1**) continue to apply on and after exit day as they applied immediately before exit day (subject to any amendments or variations published under that paragraph)."

(4) In paragraph (3) —

(a) for "Regulation 51(2)" substitute "Paragraphs (2) to (8) of regulation 51"; and

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

(**1**) The guidelines are available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.