STATUTORY INSTRUMENTS

2019 No. 775

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

PART 5

Amendment of Part 5 (marketing authorisations)

[F1Substitution of regulation 53 (applications relating to similar biological medicinal products)

58. For regulation 53 substitute—

"**Application for UKMA(NI) relating to similar biological medicinal products**

53.—(1) This regulation applies if an applicant for a UKMA(NI) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of any of the reasons described in Article 10(4) of the 2001 Directive.

(2) The applicant must provide information in accordance with Article 10(4) and (6) of the 2001 Directive.

(3) Paragraphs (2) to (4) of regulation 51 apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Application for UKMA(GB) relating to similar biological medicinal products

53A.—(1) This regulation applies if an applicant for a UKMA(GB) for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product.

(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 a reference medicinal product which is or has been authorised for not less than eight years—

(i) under regulation 49(1)(a), or

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

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

(3) 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 (4), or (as the case may be) as mentioned in paragraph (5).

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

(5) Unless replaced by guidelines published under paragraph (4), the guidelines published by the EMA under Article 10(4) of the 2001 Directive continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(6) Paragraphs (4) to (12) of regulation 51A apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.

Application for UKMA(UK) relating to similar biological medicinal products

53B.—(1) This regulation applies in relation to an application for a UKMA(UK) for a biological medicinal product.

(2) Where the application relies on a reference medicinal product which is the subject of—

(a) a UKMA(UK), the provisions of regulation 53 apply in respect of the application;

(b) a separate UKMA(GB) and UKMA(NI), paragraphs (3) to (5) apply.

(3) Subject to paragraph (4), the applicant 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 only after the expiry of both—

(a) the period referenced in the applicable Article referred to regulation 53(1), in relation to the UKMA(NI) for the reference medicinal product; and

(b) the period specified in regulation 53A(1), in relation to the UKMA(GB) for the reference medicinal product.

(4) Where the applicant for a biological medicinal product is not able to show that product meets a condition for its being a generic version of a similar medicinal product because of differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference medicinal product, the applicant must provide the results of the appropriate pre-clinical tests or clinical trials relating to the differences.

(5) The type and quantity of supplementary data to be provided by the applicant under paragraph (4) 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 (6), or (as the case may be) as mentioned in paragraph (7).

(6) The licensing authority may publish guidelines concerning the type and quantity of supplementary data to be provided by an applicant under paragraph (4).

(7) Unless replaced by guidelines published under paragraph (6), the guidelines published by the EMA under Article 10(4) of the 2001 Directive continue to apply on and after IP completion day as they applied immediately before IP completion day (subject to any amendments or variations published under that paragraph).

(8) Paragraphs (4) and (5) of regulation 51B apply to the application as they apply in relation to an application made in accordance with paragraph (1) of that regulation.”.**]**

Textual Amendments

F1 Reg. 58 substituted (31.12.2020 immediately before IP completion day) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**

Commencement Information

I1 Reg. 58 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 58.