STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Application for UK marketing authorisation

[F1Application 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.**]**

Textual Amendments

F1 Regs. 53-53B substituted for reg. 53 (31.12.2020) by S.I. 2019/775, regs. 1, **58** (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 2 para. 43**)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 53.