DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 5

Amendment of Part 5 (marketing authorisations)

Validity of conditional marketing authorisation and variation of a UK marketing authorisation

72. After regulation 65A(**1**), insert—

"**Validity of conditional marketing authorisation**

65B.—(1) A conditional marketing authorisation remains in force—

(a) for an initial period of one year beginning with the date on which it is granted; and

(b) if it is renewed in accordance with regulation 66B, for further periods of one year beginning with the date on which the renewal is granted.

(2) If an application for the renewal or further renewal of a conditional marketing authorisation is made in accordance with regulation 66B the authorisation remains in force until the licensing authority notifies the applicant of its decision on the application.

Variation of a UK marketing authorisation

65C.—(1) A UK marketing authorisation holder may apply to vary the authorisation.

(2) Any such application must be made in accordance with Schedule 10A.

(3) Schedule 10A does not apply to the transfer of a UK marketing authorisation from one person to another.

(4) The licensing authority may publish guidance on the details of the various categories of variations, on the operation of the procedures laid down in Schedule 10A, and on the documentation to be submitted pursuant to those procedures.

(5) Any guidance referred to in paragraph (4) must be regularly reviewed and, when necessary, updated.

(6) Unless replaced by guidelines published under paragraph (4), the guidelines published by the Commission under Article 4 of Regulation (EC) No 1234/2008(**2**) which applied immediately before exit day, insofar only as they concern applications under Chapter IIa of that Regulation, continue to apply to—

(**1**) Regulation 65A was inserted by S.I. 2014/1878.

(**2**) 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.

(a) applications made under regulation 65C on or after exit day; or

(b) applications made before exit day to which regulation 65C and Schedule 10A apply by virtue of Parts 3 and 5 of Schedule 33A.

(7) The Ministers may by regulations amend Schedule 10A.".