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 49 (application for grant of UK marketing authorisation or parallel import licence)

48.—(1) Regulation 49(**1**) is amended as follows.

(2) In paragraph (1), after "regulation 58," insert "58C, 58E, 58F and 58G,".

(3) After paragraph (1) insert—

"(1A) The licensing authority may only grant a parallel import licence if it is able to obtain the information necessary, whether from a competent authority of an EEA State or otherwise, to satisfy itself that the medicinal product to be imported—

(a) has been granted an EU marketing authorisation or a marketing authorisation under the 2001 Directive; and

(b) is essentially similar to a product that has already been granted a UK marketing authorisation.".

(4) In paragraph (3), for "European Union" substitute "United Kingdom."

(5) After paragraph (3) insert—

"(3A) An application for a parallel import licence may not be made by—

(a) the holder of the marketing authorisation, within the meaning of the 2001 Directive, or the EU marketing authorisation, in respect of the relevant medicinal product to be imported; or

(b) a company which is in the same group as the holder of that marketing authorisation.".

(6) At the end insert—

"(9) In this regulation "group" has the same meaning as in Part 15 of the Companies Act 2006(**2**) (see section 474(1) of that Act).".

(**1**) Regulation 49 was amended by S.I. 2014/1878.
(**2**) 2006 c.46.