
DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 4

Amendment of Part 4 (requirement for authorisation)

Amendment of regulation 46 (requirement for authorisation)

- 45.**—(1) Regulation 46 is amended as follows.
- (2) In paragraph (2)—
- (a) in sub-paragraph (a), before “marketing authorisation”, insert “UK”;
 - (b) at the end of sub-paragraph (b), insert “or”; and
 - (c) omit sub-paragraph (d) (and “or” immediately preceding it).
- (3) In paragraph (3), before “European Economic Area” insert “United Kingdom or the”.
- (4) In paragraph (6)—
- (a) in sub-paragraph (a), before “marketing authorisation”, insert “UK”;
 - (b) at the end of sub-paragraph (b), insert “or”; and
 - (c) omit sub-paragraph (d) (and “or” immediately preceding it).
- (5) In paragraph (7), omit sub-paragraph (b) (and “and” immediately preceding it).
- (6) In paragraph (9), before “European Economic Area” insert “United Kingdom or the”.
- (7) In paragraph (11)(a), before “European Economic Area” insert “United Kingdom or the”.

Amendment of regulation 47 (breach of requirement)

- 46.**—(1) Regulation 47 is amended as follows.
- (2) In paragraphs (3) and (4), before “European Economic Area”, insert “United Kingdom or the”.
- (3) In paragraph (6), for “marketing authorisation, certificate of registration, traditional herbal registration or Article 126a authorisation”, substitute “UK marketing authorisation, certificate of registration or traditional herbal registration”.