DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 17

Amendment of Part 16 (enforcement)

Amendment of regulation 322 (validity of proceedings)

219. In regulation 322(1)—

(a) for ", 7" substitute "or 7"; and

(b) omit "or 8 (Article 126a authorisations)".

Amendment of regulation 323 (enforcement in England, Wales and Scotland)

220.—(1) Regulation 323(**1**) is amended as follows.

(2) In paragraph (1) omit "and the relevant EU provisions".

(3) In paragraph (3)—

(a) at the end of sub-paragraph (b) insert "and"; and

(b) omit sub-paragraph (d).

(4) Omit paragraph (4A).

Amendment of regulation 327 (powers of inspection, sampling and seizure)

221.—(1) Regulation 327(**2**) is amended as follows.

(2) In paragraph (1)(c)—

(a) in paragraph (v), insert "UK" before "marketing authorisation";

(b) insert "or" at the end of paragraph (vi);

(c) omit paragraph (viii) (and "or" immediately preceding it).

(3) In paragraph (2)—

(a) in sub-paragraph (g)—

(i) in paragraph (ii), after "Part 11" insert "or Schedule 12A" and insert "and" at the end, and

(ii) omit paragraphs (iii), (iv) and (v); and

(b) omit sub-paragraph (h).

(4) Omit paragraph (4A).

(**1**) Regulation 323 was amended S.I. 2019/62.
(**2**) Regulation 327 was amended by S.I. 2013/1855 and 2019/62.

(5) In paragraph (5)—

(a) in sub-paragraph (a) for ", (g) or (h)" substitute "or (g)"; and

(b) in sub-paragraph (b) omit " or (4A)".

Amendment of regulation 331 (findings and reports of inspections)

222.—(1) Regulation 331 is amended as follows.

(2) In paragraph (1)—

(a) insert "UK" before "marketing authorisation"; and

(b) omit sub-paragraph (c) (and "and" immediately preceding it).

(3) In paragraph (4) for sub-paragraph (c) substitute—

"(c) in the case of a holder of a UK marketing authorisation or traditional herbal registration, Part 11 (pharmacovigilance).".

Insertion of regulation 331A (guidelines on inspections)

223. After regulation 331 (finding and reports of inspections) insert—

"**Guidelines on inspections**

331A.—(1) The licensing authority may publish guidelines specifying the principles applicable to inspections referred to in this Part.

(2) Guidelines under paragraph (1) may include the form and content of reports under regulation 331 and of certificates of good manufacturing practice or good distribution practice.

(3) Until the licensing authority exercises its power under paragraph (1), the guidelines adopted by the European Commission under Article 111a of the 2001 Directive, as they had effect immediately before exit day(**3**), are to continue to apply.".

(**3**) 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.