DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 3

Amendment of Part 3 (manufacture and distribution of medicinal products and active substances)

Amendment of regulation 45A (brokering in medicinal products)

38.—(1) Regulation 45A(**1**) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a) for paragraphs (i) and (ii) substitute—

"(i) by the licensing authority, or

(ii) by an appropriate authority responsible for the licensing of medicinal products in an approved country for import,";

(b) in sub-paragraph (b)—

(i) in paragraph (i), for "a competent authority of a member State" substitute "the licensing authority",

(ii) in paragraph (ii), omit "except where the person is validly registered with the competent authority of another EEA State", and

(iii) in paragraph (iii), for "published by the European Commission in accordance with Article 84 of the 2001 Directive" substitute "which apply under, or by virtue of, regulation C17".

(3) In paragraph (2)—

(a) in sub-paragraph (a), for "a competent authority of a member State" substitute "the licensing authority";

(b) in sub-paragraph (c), for "competent authority of a member State" substitute "licensing authority".

(4) Omit paragraph (3).

(**1**) Regulation 45A was inserted by S.I. 2013/1855.