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 Schedule 3 (applications for licences under Part 3)

18.—(1) Schedule 3 is amended as follows.

(2) In paragraph 1(2)(g), for "marketing authorisation, Article 126a authorisation," substitute "UK marketing authorisation".

(3) In paragraph 2(1), for "state other than an EEA state" substitute "country other than an approved country for import".

(4) In paragraph 3—

(a) in sub-paragraph (2)(d) at the end insert "or the responsible person (import)".

(b) in sub-paragraph (3)(b)—

(i) in paragraph (i), insert "UK" before "marketing authorisation",

(ii) omit paragraph (iv), and

(iii) after paragraph (iii) insert—

"(v) an authorisation granted by an authority in a country other than the United Kingdom to sell or supply the medicinal product in that other country;";

(c) in sub-paragraph (3)(d)—

(i) in paragraph (i) omit "or",

(ii) in paragraph (ii) for "etc);" substitute "etc), or",

(iii) at the end insert—

"(iii) to be distributed by means of export to an approved country for import;"; and

(d) for sub-paragraph (4) substitute—

"(4) In sub-paragraph (2)(d)—

"the responsible person" means the person who has the functions described in regulation 45(2);

"the responsible person (import)" means the person who has the functions described in regulation 45AA(4).".