DRAFT STATUTORY INSTRUMENTS

2022 No.

The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

Amendment of regulation 43

17.—(1) Regulation 43(**1**) (qualified persons) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (b), after "United Kingdom," insert "except, in relation to a EAMS medicinal product, to the extent that conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) of the 2012 Regulations provide otherwise,"; and

(b) after "in paragraph" insert "(1A) or".

(3) After paragraph (1), insert—

"(1A) The qualified person is responsible for ensuring that, in relation to an EAMS medicinal product, if conditions attached to the scientific opinion in respect of that product in accordance with regulation 167C(2)(c) of the 2012 Regulations require the qualified person to carry out any duties in respect of that product, that qualified person carries out those duties.".

(4) In paragraph (4), after "with paragraph" insert "(1A) or".

(**1**) Amended by S.I. 2019/744.