DRAFT STATUTORY INSTRUMENTS

2022 No.

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

Amendment of Schedule 7

18.—(1) Schedule 7 (standard provisions for manufacturing authorisations) is amended as follows.

(2) In Part 2 (provisions which may be incorporated in an authorisation relating to the manufacture or assembly of investigational medicinal products)—

(a) in paragraph 1(a), after "investigational medicinal products" insert "or EAMS medicinal products";

(b) in paragraph 2, after "investigational medicinal products", at each place where it occurs, insert "or EAMS medicinal products";

(c) in paragraph 9(**1**)—

(i) after "investigational medicinal product" at both places where it occurs, insert "or EAMS medicinal product", and

(ii) after "clinical trials" insert "or as part of the Early Access to Medicines Scheme";

(d) in paragraph 10, after "investigational medicinal product" insert "or EAMS medicinal product";

(e) in paragraph 11, after "investigational medicinal product", at each place where it occurs, insert "or EAMS medicinal product";

(f) in paragraph 12, after "investigational medicinal product", at both places where it occurs, insert "or EAMS medicinal product";

(g) in paragraph 13(**2**), after sub-paragraph (a) insert—

"(aa) amending the conditions attached to or revoking an EAMS scientific opinion;";

(h) in paragraph 14, for "regulation 43(2)" substitute "regulation 43(1A) or (2)"; and

(i) after paragraph 14 insert—

"**14A.** The holder of the authorisation shall only manufacture or assemble EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(3) In Part 3 (provisions which may be incorporated in an authorisation relating to the importation of investigational medicinal products)—

(a) in paragraph 1, after "investigational medicinal products", at each place where it occurs, insert "or EAMS medicinal products";

(b) in paragraph 3, after "investigational medicinal products" insert "or EAMS medicinal products";

(**1**) Amended by S.I. 2012/1916.
(**2**) Amended by S.I. 2012/1916.

(c) in paragraph 6(**3**)—

(i) after "investigational medicinal product", at both places where it occurs, insert "or EAMS medicinal product", and

(ii) after "in clinical trials" insert "or as part of the Early Access to Medicines Scheme";

(d) in paragraph 8, after sub-paragraph (a) insert—

"(aa) amending the conditions attached to or revoking an EAMS scientific opinion;";

(e) in paragraph 9, for "regulation 43(2)" substitute "regulation 43(1A) or (2)"; and

(f) after paragraph 9 insert—

"**9A.** The holder of the authorisation shall only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(**3**) Amended by S.I. 2012/1916.