DRAFT STATUTORY INSTRUMENTS

2022 No.

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

Amendment of Schedule 4

14.—(1) Schedule 4 (standard provisions of licences under Part 3) is amended as follows.

(2) After paragraph 14A(**1**), insert—

"**14B.** A licence holder may 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 paragraph 22(**2**)—

(a) in sub-paragraph (5), after "special medicinal products" insert "or EAMS medicinal products";

(b) in sub-paragraph (7), after "special medicinal product" insert "or EAMS medicinal product";

(c) in sub-paragraph (8) after "special medicinal product" insert "or EAMS medicinal product"; and

(d) in sub-paragraph (9), after "special medicinal product" insert "or EAMS medicinal product".

(4) After paragraph 23A(**3**), insert—

"**23B.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(5) After paragraph 33, insert—

"**33A.** A licence holder may only import EAMS medicinal products if and to the extent that such products are required for the Early Access to Medicines Scheme.".

(6) In paragraph 37, after "special medicinal products" insert "or EAMS medicinal products".

(7) In paragraph 39, after "special medicinal product" insert "or EAMS medicinal product".

(8) In paragraph 40, after "special medicinal product" insert "or EAMS medicinal product".

(9) In paragraph 41, after "special medicinal product" insert "or EAMS medicinal product".

(**1**) Inserted by S. 2019/775.
(**2**) Amended by S.I. 2019/775.
(**3**) Inserted by S.I. 2019/775.