DRAFT STATUTORY INSTRUMENTS

2022 No.

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

Amendment of Schedule 1

12.—(1) Schedule 1 (further provisions for classification of medicinal products) is amended as follows.

(2) In Part 1(**1**) (descriptions of certain medicinal products to be available only on prescription), in paragraph 1—

(a) omit "and" at the end of sub-paragraph (g);

(b) insert "; and" at the end of sub-paragraph (h); and

(c) after sub-paragraph (h) insert—

"(i) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, the product is classified as a prescription only medicine.".

(3) In Part 2(**2**) (descriptions of certain medicinal products to be available only from a pharmacy), in paragraph 3—

(a) omit "and" at the end of sub-paragraph (c);

(b) insert "; and" at the end of sub-paragraph (d); and

(c) after sub-paragraph (d) insert—

"(e) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, it is only to be available from a pharmacy.".

(**1**) Amended by S.I. 2014/490, 2019/775 and 2020/1125.
(**2**) Amended by S.I. 2019/775 and 2020/1125.