
DRAFT STATUTORY INSTRUMENTS

2022 No.

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

Amendment of regulation 37

5.—(1) Regulation 37(1) (manufacturing and assembly) is amended as follows.

(2) In paragraph (6)—

(a) omit “and” at the end of sub-paragraph (a); and

(b) after sub-paragraph (a) insert—

“(aa) in the case of a product for supply as an EAMS medicinal product, the conditions attached to the EAMS scientific opinion in respect of the product; and”.

(3) In paragraph (10), after “applies” insert “or an EAMS medicinal product to which regulation 167E(1) to (4) (EAMS medicinal product: manufacture, assembly, importation, distribution and supply) applies”.