
STATUTORY INSTRUMENTS

2023 No. 437

The Human Medicines (Amendment) Regulations 2023

Insertion of new regulation 345A (obligation on licensing authority to maintain list of medicinal products to which derogations have applied)

5. After regulation 345 insert—

“Obligation on licensing authority to maintain list of medicinal products to which derogations have applied

345A.—(1) The licensing authority must publish a list of medicinal products to which the derogations described in Articles 5a, 8(2a) and (2b), 18a, 20 (second paragraph), 40(1a) and (3a), 48(3) and 104(3) of the 2001 Directive have applied.

(2) The licensing authority must update the list referred to in paragraph (1) at least every six months.”.