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DRAFT STATUTORY INSTRUMENTS

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**2019 No.**

The Human Medicines (Amendment  
etc.) (EU Exit) Regulations 2019

PART 3

Amendment of Part 3 (manufacture and distribution  
of medicinal products and active substances)

**Amendment of Schedule 5 (review upon oral representations)**

- 22.**—(1) Schedule 5(1) is amended as follows.
- (2) In paragraph 1(2)(e), 3(11)(b) and 5(2)(d) after—
- (a) “UK marketing authorisation,” in each place it appears, insert “parallel import licence,”;  
and
  - (b) “an authorisation,” or “the authorisation,” in each place it appears, insert “licence.”
- (3) In paragraph 3 omit sub-paragraph (11)(b)(iii).
- (4) In paragraph 5 omit sub-paragraph (2)(c).