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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 regulation 45 (requirement as to responsible persons)**

**36.**—(1) Regulation 45 is amended as follows.

(2) In paragraph (1), for “The licence holder” insert substitute “Subject to regulation 45AA, the licence holder”.

(3) In paragraph (2)(b) for “marketing authorisations, Article 126a authorisations” substitute “UK marketing authorisations”.