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DRAFT STATUTORY INSTRUMENTS

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**2019 No.**

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

PART 7

Amendment of Part 7 (Traditional Herbal Registrations)

**Amendment of regulation 149 (urgent safety restrictions)**

**131.**—(1) Regulation 149 is amended as follows.

(2) In the heading to regulation 149, at the end insert “: offences”.

(3) In sub-paragraph (a), for “or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008” substitute “in accordance with regulation 148A(1)”.

(4) In sub-paragraph (b), for “or the European Commission under Article 22(2) of that Regulation” substitute “in accordance with regulation 148A(2)”.

(5) For sub-paragraph (c), substitute—

“(c) fails to submit an application for variation of the traditional herbal registration to the licensing authority in accordance with regulation 148A(4) before the end of the period of 15 days beginning with the day after—

(i) the taking under regulation 148A(1), or

(ii) the imposition under regulation 148A(2),

of an urgent safety restriction.”.