DRAFT STATUTORY INSTRUMENTS

2019 No.

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

PART 10

Amendment of Part 10 (exceptions to requirement for marketing authorisations etc)

Amendment of regulation 168 (use of non-prescription medicines in the course of a business)

135. In regulation 168, in paragraph (8)—

(a) in sub-paragraph (a), for "EEA State" substitute "approved country for import"; and

(b) for sub-paragraph (b) substitute—

"(b) imported from an approved country for import—

(i) it is manufactured or assembled in that country by a person who is the holder of an authorisation in that country in relation to its manufacture or assembly, and

(ii) it is imported by the holder of a wholesale dealer's licence under Part 3 that includes the import of a medicinal product from such a country.".

Amendment of regulation 169 (mixing of general sale medicinal products)

136. In regulation 169(9)(a), insert "UK" before "marketing authorisation".

Amendment of regulation 171 (exempt advanced therapy medicinal products)

137. In paragraph regulation 171(2)(c) for "Regulation (EC) No 726/2004" substitute "regulation 49(1)".

Amendment of regulation 173 (exemption for certain radiopharmaceuticals)

138. In regulation 173(c), insert "UK" before "marketing authorisation".