
STATUTORY INSTRUMENTS

2019 No. 62

The Human Medicines (Amendment) Regulations 2019

Amendment of regulation 327 (powers of inspection, sampling and seizure)

15. In regulation 327(1)—

(a) after sub-paragraph (2)(g) insert—

“(h) information and documents relating to compliance with the requirements of Commission Regulation 2016/161C.”;

(b) after paragraph (4) insert—

“(4A) The inspector may for the purposes specified in paragraph (1) require a legal entity established to set up and manage the repositories system pursuant to Article 31 of Commission Regulation 2016/161, or a person employed in connection with such a entity, to produce information or documents relating to the repositories system which are in the entity’s possession or under the entity’s control.”;

(c) in sub-paragraph (5)(a), for “or (g)” substitute “, (g) or (h),”; and

(d) in sub-paragraph (5)(b), after “paragraph (4)” insert “or (4A)”.