
STATUTORY RULES OF NORTHERN IRELAND

2019 No. 10

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).”;

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