
STATUTORY RULES OF NORTHERN IRELAND

2019 No. 10

The Human Medicines (Amendment) Regulations 2019

Amendment of regulation 42 (conditions for wholesale dealer's licence)

6. In regulation 42(1), after paragraph (3) insert—

“(4) The requirements and obligations contained in a provision of Commission Regulation 2016/161 listed in paragraph (5) have effect as if they were provisions of a wholesale dealer's licence under this Part.

(5) The provisions mentioned in paragraph (4) are—

- (a) Article 10 (verification of the safety features) insofar as it relates to wholesalers;
- (b) Article 11 (verification of the authenticity of the unique identifier) insofar as it relates to wholesalers;
- (c) Article 12 (unique identifiers which have been decommissioned);
- (d) Article 13 (reversing the status of a decommissioned unique identifier) insofar as it relates to wholesalers;
- (e) Article 20 (verification of the authenticity of the unique identifier), subject to the exemption contained in Article 21 (derogations from Article 20(b));
- (f) Article 22 (decommissioning of unique identifiers); and
- (g) Article 24 (actions to be taken in case of tampering or suspected falsification).”.