
STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

The Human Medicines (Amendment) (No. 2) Regulations 2014

Amendment of regulation 68

11.—(1) Regulation 68 (revocation, variation and suspension of UK marketing authorisation) is amended as follows.

(2) For paragraph (4) substitute—

“(4) Condition C is that the licensing authority thinks that there has been a breach of—

- (a) a term of the authorisation or licence;
- (b) in the case of a UK marketing authorisation, a requirement imposed by Part 13 (packaging and leaflets); or
- (c) in the case of a parallel import licence, a requirement in relation to packaging and leaflets imposed by the licensing authority.”

(3) For paragraph (5) substitute—

“(5) Condition D is that the licensing authority thinks that a condition to which—

- (a) the UK marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of UK marketing authorisations or parallel import licence: general); or
- (b) the UK marketing authorisation is subject by virtue of regulations 60 (conditions of UK marketing authorisations: exceptional circumstances) or 61 (conditions of UK marketing authorisations: new obligations post-authorisation),

has not been fulfilled.”

(4) In paragraph (13) for “This” substitute “Except in the case of a parallel import licence, this”.