
STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

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

Substitution of regulation 97

17. For regulation 97 (breach of pharmacovigilance condition) substitute—

“Breach of pharmacovigilance condition

97.—(1) The holder of a marketing authorisation or a parallel import licence is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation or parallel import licence is subject by virtue of regulation 59 (conditions of a UK marketing authorisation or parallel import licence: general).

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to comply with a condition to which the marketing authorisation is subject by virtue of regulation 60 (conditions of a UK marketing authorisation: exceptional circumstances) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation).”