

---

STATUTORY INSTRUMENTS

---

**2014 No. 1878**

**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).”