
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Offences relating to EU marketing authorisations

EU marketing authorisations: breach of pharmacovigilance condition etc

86.—(1) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to comply with—

- (a) any obligation to which the marketing authorisation is subject by virtue of Articles 10a(1) or 14(7); or
- (b) any condition to which the authorisation is subject by virtue of Article 14(8),

of Regulation [\(EC\) No 726/2004](#).

(2) The holder of an EU marketing authorisation is guilty of an offence if the holder fails to incorporate into the risk management system for the product as required by Article 14a of Regulation [\(EC\) No 726/2004](#)—

- (a) any recommendation referred to in Article 9(4)(c), (ca), (cb) or (cc);
- (b) any obligation to which the authorisation is subject by virtue of Articles 10a(1) or 14(7); or
- (c) any condition to which the marketing authorisation is subject by virtue of Article 14(8),

of Regulation [\(EC\) No 726/2004](#).