STATUTORY INSTRUMENTS

# 2012 No. 1916

# The Human Medicines Regulations 2012

## PART 5

## Marketing authorisations

*Offences relating to specific requirements*

**Failure to provide information on marketing authorisations to EMA**

**79.**—(1) The holder of a marketing authorisation is guilty of an offence if the holder—

(a) has not submitted information to the EMA as required by Article 57(2)(b) of Regulation (EC) No 726/2004 (information on all existing medicinal products for human use authorised or registered in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted before 2nd July 2012; and

(b) fails to do so as soon as is reasonably practicable after the coming into force of these Regulations.

(2) The holder of a marketing authorisation is guilty of an offence if the holder fails to submit information to the EMA as required by Article 57(2)(c) of Regulation (EC) No 726/2004 (information on any new or varied authorisations granted in the EU) in relation to any medicinal product that is the subject of a marketing authorisation granted on or after 2nd July 2012 as soon as is reasonably practicable after the grant of the authorisation.

**Urgent safety restrictions**

**80.** The holder of a marketing authorisation is guilty of an offence if the holder —

(a) fails to inform the licensing authority or the European Commission in accordance with Article 22(1) of Regulation (EC) No 1234/2008 that the holder has taken urgent safety restrictions on the holder's own initiative;

(b) fails to implement an urgent safety restriction imposed on the holder by the licensing authority or the European Commission under Article 22(2) of that Regulation; or

(c) fails to submit an application for variation of the marketing authorisation to the licensing authority or the European Commission in accordance with Article 22(3) of that Regulation before the end of a period of fifteen days beginning on the day after—

(i) the taking under Article 22(1) or, as the case may be,

(ii) the imposition under Article 22(2),

of that Regulation of an urgent safety restriction.