STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Offences relating to advanced therapy medicinal products

Offences in connection with risk management systems and traceability systems

87.—(1) The holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the holder fails to—

(a) submit an additional report evaluating the effectiveness of a risk management system and the results of studies within the period of 21 days beginning on the day following receipt of a request made under the second sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, or such longer period as the EMA may specify; or

(b) include in any periodic safety update report referred to in Article 28(2) of Regulation (EC) No 726/2004 an evaluation of the effectiveness of a risk management system or of the results of any study performed pursuant to the first sub-paragraph of Article 14(2) of Regulation (EC) No 1394/2007, as required by the third sub-paragraph of Article 14(2).

(2) A person who is, or who immediately before its revocation or withdrawal was, the holder of an EU marketing authorisation for an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) establish and maintain a traceability system in accordance with the requirements set out in Article 15(1) of Regulation (EC) No 1394/2007;

(b) where the product contains human cells or tissues, to ensure that the traceability system is complementary to and compatible with the requirements laid down in Articles 8 and 14 of Directive 2004/23/EC, as regards human cells and tissues other than blood cells, and Articles 14 and 24 of Directive 2002/98/EC, as regards blood cells; or

(c) to keep the data to which the traceability system relates in accordance with the requirements of Article 15(4) of Regulation (EC) No 1394/2007.

Offence concerning data for advanced therapy medicinal products

88.—(1) A person who is, or immediately before its revocation or suspension was, the holder of an EU marketing authorisation relating to an advanced therapy medicinal product is guilty of an offence if the person fails to—

(a) keep the data referred to in Article 15(1) of Regulation (EC) No 1394/2007 in accordance with the requirements of Article 15(4) of that Regulation; or

(b) transfer the data referred to in Article 15(1) to the EMA in the event of that person's bankruptcy or liquidation in accordance with Article 15(5),

but this is subject to paragraph (2).

(2) Paragraph (1)(b) does not apply if—

(a) the person is bankrupt or in liquidation and has transferred the data to another person; or

(b) the period for which the person was required to keep the data in accordance with the requirements of Article 15(4) mentioned in paragraph (1)(a) has expired.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Offences relating to advanced therapy medicinal products.