
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 10

Exceptions to requirement for marketing authorisation etc

Offences

Offences relating to exceptions

175.—(1) A person to whom this paragraph applies is guilty of an offence if the person provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a medicinal product that is false or misleading in a material particular.

(2) Paragraph (1) applies to any person who for the purposes of regulation 167 (special patient needs)—

- (a) sells or supplies the product; or
- (b) provides a specification for the product.

(3) A person is guilty of an offence if the person fails to—

- (a) maintain any record required by regulation 170(1) (records in connection with special medicinal products etc);
- (b) make any record available as required by regulation 170(2); or
- (c) notify the licensing authority of any suspected serious adverse reaction as required by regulation 170(3).