
STATUTORY RULES OF NORTHERN IRELAND

2014 No. 324

The Human Medicines (Amendment) (No. 2) Regulations 2014

Insertion of regulation 95A

16. After regulation 95 (offences in connection with marketing authorisation application) insert—

“Offences in connection with parallel import licence application

95A. A person is guilty of an offence if, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal product, the person—

- (a) fails to provide the licensing authority with any information that is relevant to the evaluation of the safety, quality or efficacy of the product; or
- (b) provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of the product but that is false or misleading in a material particular.”