
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

General provisions relating to offences

General offence of breach of provision of this Part

98.—(1) A person is guilty of an offence if that person commits a breach of a provision in this Part.

(2) A breach of a provision in this Part includes any—

- (a) failure by the holder of a marketing authorisation [^{F1}or parallel import licence] to comply with any requirement or obligation in this Part;
- (b) contravention by any person of any prohibition in this Part; or
- (c) failure to comply with any requirement imposed on a person by the licensing authority pursuant to this Part.

(3) Paragraph (1) is without prejudice to any offence established by any other provision in this Part.

Textual Amendments

- F1** Words in reg. 98(2)(a) inserted (E.W.S.) (1.10.2014) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2014 \(S.I. 2014/1878\)](#), regs. 1, 4 and words in reg. 98(2)(a) inserted (N.I.) (1.10.2014) by [The Human Medicines \(Amendment\) \(No. 2\) Regulations 2014 \(S.R. 2014/324\)](#), regs. 1(1), **4(2)(p)**

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 98.