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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 7**

**Traditional herbal registrations**

*Offences relating to traditional herbal registrations*

**Urgent safety restrictions**

- 149.** The holder of a traditional herbal registration 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 traditional herbal registration 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.

**Offences in connection with applications**

- 150.** A person is guilty of an offence if in the course of an application for the grant, renewal or variation of a traditional herbal registration for a traditional herbal 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 that is false or misleading in a material particular.

**Provision of false or misleading information**

**151.—(1)** The holder of a traditional herbal registration is guilty of an offence if the holder provides to the licensing authority any information that is relevant to the evaluation of the safety, quality or efficacy of a traditional herbal medicinal product but that is false or misleading in a material particular.

- (2) Paragraph (1) is without prejudice to regulation 150.

### **General offence of breach of provision of this Part**

**152.**—(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 traditional herbal registration 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.

### **Penalties**

**153.** A person guilty of an offence under this Part is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum; or
- (b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.

### **Persons liable**

**154.** If an offence under regulation 150 (offences in connection with applications) is committed by a person acting as employee or agent, the employer or principal of that person is guilty of the same offence and is liable to be proceeded against and punished accordingly.

### **Defences**

**155.**—(1) Paragraph (2) applies if the holder of a traditional herbal registration is charged with an offence under this Part in respect of anything that—

- (a) has been manufactured or assembled to the holder's order by another person; and
- (b) has been so manufactured or assembled as not to comply with the terms of the authorisation.

(2) It is a defence for the holder to prove that—

- (a) the holder communicated the terms of the registration to the other person; and
- (b) the holder did not know and could not by the exercise of reasonable care have known that those terms had not been complied with.

(3) It is a defence for a person charged with an offence consisting of a breach of regulation 142(3) or 148 or an offence under regulation 150 or 151 to prove that the person took all reasonable precautions and exercised all due diligence to avoid commission of that offence.

(4) Where evidence is adduced that is sufficient to raise an issue with respect to the defence in paragraph (3), the court or jury must presume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not.