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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*

#### **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.

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 155.