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STATUTORY INSTRUMENTS

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**2012 No. 1916**

**The Human Medicines Regulations 2012**

**PART 3**

[<sup>F1</sup>Manufacture and distribution of medicinal products and active substances]

[<sup>F1</sup>CHAPTER 4

Importation, manufacture and distribution of active substances

**[<sup>F1</sup>Offences: breach of regulations and false information**

**45U.**—(1) A person is guilty of an offence if the person imports, manufactures or distributes an active substance in breach of regulation 45M(1).

(2) A person is guilty of an offence if the person knowingly gives false information in—

- (a) a registration form received by the licensing authority under regulation 45N(1);
- (b) a notification to the licensing authority under regulation 45N(2) or 45P(4);
- (c) an application for a variation under regulation 45T(2); or
- (d) response to a notice under regulation 45T(4).

(3) A person is guilty of an offence if, without reasonable excuse, the person fails to comply with a notice under regulation 45P(6) or 45T(4).]

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**Textual Amendments**

**F1** Pt. 3 Chs. 3, 4 inserted (20.8.2013) by [The Human Medicines \(Amendment\) Regulations 2013 \(S.I. 2013/1855\)](#), regs. 1(1), 16

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 45U.