

STATUTORY INSTRUMENTS

2001 No. 3998

The Misuse of Drugs Regulations 2001

[^{F1}Orders, supply and use of cannabis-based products for administration

16A.—(1) Subject to paragraph (4), a person shall not order (whether by issuing a prescription or otherwise) a cannabis-based product for medicinal use in humans for administration, unless that product is—

- (a) a special medicinal product that—
 - (i) is not also an investigational medicinal product, but
 - (ii) is for use in accordance with a prescription or direction of a specialist medical practitioner;
- (b) an investigational medicinal product without a marketing authorisation that is for use in a clinical trial; or
- (c) a medicinal product with a marketing authorisation.

(2) Subject to paragraph (4), a person shall not supply a cannabis-based product for medicinal use in humans by way of or for the purpose of the administration of that product, unless the supply—

- (a) is pursuant to an order that complies with paragraph (1); and
- (b) is—
 - (i) in the case of a product that is a special medicinal product but is not also an investigational medicinal product, for use in accordance with a prescription or direction of a specialist medical practitioner,
 - (ii) in the case of a product that is an investigational medicinal product without a marketing authorisation, for use in a clinical trial, or
 - (iii) of a medicinal product with a marketing authorisation.

(3) A person shall not self-administer a cannabis-based product for medicinal use in humans by the smoking of the product (other than for research purposes in accordance with regulation 13);

(4) Nothing in this regulation shall have effect in relation to the order or supply of a cannabis-based product for medicinal use in humans for administration to animals for research purposes.

(5) In this regulation, “investigational medicinal product”, “marketing authorisation”, and “special medicinal product” have the same meanings as in the Human Medicines Regulations 2012.

(6) In this regulation, “specialist medical practitioner” means a doctor included in the register of specialist medical practitioners kept under section 34D of the Medical Act 1983 (the Specialist Register).]

Textual Amendments

- F1** Reg. 16A inserted (1.11.2018) by [The Misuse of Drugs \(Amendments\) \(Cannabis and Licence Fees\) \(England, Wales and Scotland\) Regulations 2018 \(S.I. 2018/1055\)](#), regs. 1(1), 4

Changes to legislation:

There are currently no known outstanding effects for the The Misuse of Drugs Regulations 2001, Section 16A.