STATUTORY INSTRUMENTS

2018 No. 1055

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

New regulation 16A of the 2001 Regulations

4. After regulation 16 of the 2001 Regulations (provisions as to supply on prescription), insert—

"**16A Orders, supply and use of cannabis-based products for administration**

(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(**1**).

(**1**) S.I. 2012/1916. See the definition of those terms in regulation 8.

(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(**2**) (the Specialist Register).".

(**2**) 1983 c. 54; section 34D was inserted by S.I. 2010/234.