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STATUTORY INSTRUMENTS

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**2013 No. 625**

**DANGEROUS DRUGS, ENGLAND AND WALES  
DANGEROUS DRUGS, SCOTLAND**

**The Misuse of Drugs (Amendment No. 2)  
(England, Wales and Scotland) Regulations 2013**

<i>Made</i>	- - - -	<i>13th March 2013</i>
<i>Laid before Parliament</i>		<i>18th March 2013</i>
<i>Coming into force</i>	- -	<i>10th April 2013</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7, 10, 22 and 31 of the Misuse of Drugs Act 1971(1).

In accordance with section 31(3) of that Act the Secretary of State has consulted with the Advisory Council on the Misuse of Drugs.

**Citation, commencement, interpretation and extent**

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2013 and shall come into force on 10<sup>th</sup> April 2013.

(2) In these Regulations the “2001 Regulations” means the Misuse of Drugs Regulations 2001(2).

(3) These Regulations extend to England and Wales and Scotland.

**Amendment of the Misuse of Drugs Regulations 2001**

2. The 2001 Regulations are amended as follows.

**Amendment of regulation 22**

3. For the heading of regulation 22 substitute “Record-keeping requirements in respect of drugs in Schedules 3 and 4”.

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(1) 1971 c. 38. Section 22 has been amended by section 177(1) of, and paragraph 12 of Schedule 4 to, the Customs and Excise Management Act 1979 (c. 2).

(2) S.I. 2001/3998. Relevant amending instruments are S.I. 2003/1432, S.I. 2003/1653, S.I. 2003/2429, S.I. 2004/1771, S.I. 2005/271, S.I. 2005/1653, S.I. 2005/2864, S.I. 2005/3372, S.I. 2006/986, S.I. 2006/1450, S.I. 2006/2178, S.I. 2007/2154, S.I. 2009/3136, S.I. 2010/1144, S.I. 2010/1799, S.I. 2011/448, S.I. 2012/277 which was not published and was revoked by S.I. 2012/385, S.I. 2012/973, S.I. 2012/1311, and S.I. 2013/176.

**4.** After regulation 22(4) insert—

“(5) Every person who is authorised by or under any provision of the Act to have in his possession or to destroy, or cause to be destroyed, the substance specified in paragraph 5 of Part 1 of Schedule 4 shall make a record of each quantity of such drug possessed or destroyed.

(6) Paragraph (5) shall not have effect in relation to—

- (a) a patient to whom the substance specified in paragraph 5 of Part 1 of Schedule 4 has been prescribed;
- (b) a constable when acting in the course of his duty as such;
- (c) a person engaged in the business of a carrier when acting in the course of that business;
- (d) a person engaged in the business of a postal operator (within the meaning of Part 3 of the Postal Services Act 2011)(3) when acting in the course of that business;
- (e) an officer of customs and excise when acting in the course of his duty as such;
- (f) a person engaged in the work of any laboratory to which the substance specified in paragraph 5 of Part 1 of Schedule 4 has been sent for forensic examination when acting in the course of his duty as a person so engaged; and
- (g) a person engaged in conveying the substance specified in paragraph 5 of Part 1 of Schedule 4 to a person who may lawfully have that substance in his possession.”.

**Amendment of regulation 27**

**5.** In regulation 27(5) (destruction of controlled drugs) for “regulation 22(2) or (3) or 24(3)” substitute “regulation 22(2), (3) or (5) or 24(3)”.

**Amendment of Schedule 1**

**6.** In paragraph 1(a) of Schedule 1 (controlled drugs subject to the requirements of regulations 14, 15, 16, 18, 19, 20, 23, 26 and 27) after “Cannabis” insert “(not being the substance specified in paragraph 5 of Part 1 of Schedule 4)”.

**Amendment of Schedule 4**

**7.** After paragraph 4 of Part 1 of Schedule 4 (controlled drugs subject to the requirements of regulations 22, 23, 26 and 27) insert—

“**5.** A liquid formulation—

- (a) containing a botanical extract of cannabis—
  - (i) with a concentration of not more than 30 milligrams of cannabidiol per millilitre, and not more than 30 milligrams of delta-9-tetrahydrocannabinol per millilitre, and
  - (ii) where the ratio of cannabidiol to delta-9-tetrahydrocannabinol is between 0.7 and 1.3,
- (b) which is dispensed through a metered dose pump as a mucosal mouth spray, and
- (c) which was approved for marketing by the Medicines and Healthcare Products Regulatory Agency on 16<sup>th</sup> June 2010(4)

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(3) 2011 c. 5.

(4) The approval may be accessed at <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con084961.pdf>.

Home Office  
13th March 2013

*Jeremy Browne*  
Minister of State

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations provide, in regulations 6 and 7, for the cannabis-based medicine “Sativex” to be placed in Part 1 of Schedule 4 to the Misuse of Drugs Regulations 2001. Regulation 4 inserts new paragraph (5) into regulation 22 which provides that a person, other than those persons specified in new paragraph (6), who is authorised to possess or to destroy, or cause to be destroyed, “Sativex” shall make a record of the quantity possessed or destroyed, and regulation 5 excepts a person who makes such a record under new regulation 22(5) from the requirements relating to the destruction of controlled drugs contained in regulation 27(1) or (3) of the Misuse of Drugs Regulations 2001.

A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available and is published with the Explanatory Memorandum alongside the instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).