STATUTORY INSTRUMENTS

2020 No. 559

DANGEROUS DRUGS

The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2020

| Made | 1st June 2020 |
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| Laid before Parliament | 3rd June 2020 |
| Coming into force in accordance with regulation $1(1)$ | |

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 7(1)(a) and 31(1)(a) 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 and extent

1.—(1) These Regulations may be cited as the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2020 and come into force on the 21st day after the day on which they are laid before Parliament.

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

Amendment of the Misuse of Drugs Regulations 2001

2.—(1) The Misuse of Drugs Regulations 2001(2) are amended as follows.

(2) In regulation 2 (interpretation), in the definition of "cannabis-based product for medicinal use in humans"(3), for "Schedule 4 applies" substitute—

"Schedule 4, or paragraph 10 of Schedule 5, applies".

(3) 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), for "Cannabinol derivatives not being dronabinol or its stereoisomers" substitute—

"Cannabinol derivatives not being-

- (i) dronabinol or its stereoisomers; or
- (ii) the substance specified in paragraph 10 of Schedule 5".

^{(1) 1971} c. 38.

⁽**2**) S.I. 2001/3998.

⁽³⁾ This definition was inserted by S.I. 2018/1055.

(4) In Schedule 5 (controlled drugs excepted from the prohibition on importation, exportation and possession and subject to the requirements of regulations 24 and 26), after paragraph 9 insert—

- "10. A liquid formulation—
 - (a) containing cannabidiol obtained by extraction and purification from cannabis;
 - (b) where the concentration of—
 - (i) delta-9-tetrahydrocannabinol is not more than 0.1 milligram per millilitre; and
 - (ii) cannabidiol is 95-105 milligrams per millilitre;
 - (c) which is presented in a bottle, as an oral solution for oral administration; and
 - (d) which was approved for marketing by the European Commission on 19th September 2019. "(4).

1st June 2020

Kit Malthouse Minister of State Home Office

⁽⁴⁾ https://ec.europa.eu/health/documents/community-register/html/h1389.htm; a hard copy can be obtained from the Home Office at 2 Marsham Street, London SW1P 4DF.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) to provide for a specified cannabis-based medicine called Epidyolex to be placed in Schedule 5 of the Regulations. The effect of this is that the specified medicine is exempt from the prohibitions on import, export and possession under sections 3 and 5 of the Misuse of Drugs Act 1971.

A full impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector is published with the Explanatory Memorandum alongside this instrument on www.legislation.gov.uk; copies may be obtained from the Home Office at 2 Marsham Street, London SW1P 4DF.