

EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENTS) (CANNABIS AND LICENCE FEES) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2018

2018 No. 1055

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This measure will make cannabis-based products available to be prescribed for medicinal use. It will amend the Misuse of Drugs Regulations 2001 (“the 2001 Regulations”) and the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 (“the 2015 Designation Order”). This instrument also amends the Misuse of Drugs (Licence Fees) Regulations 2010 (“the 2010 Regulations”) to provide for waiver of licence fees.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 This is the first occasion on which the powers to vary a designation order and reschedule products or substances have been used to specify a product by reference to both its form and purpose, as well as to its composition. However, this is not the first time that a cannabis-based medicinal product has been exempted from designation and rescheduled under the 2001 Regulations by detailed reference to its form. Sativex, is a cannabis-based formulation for treatment of specified conditions, by means of a buccal spray. The Misuse of Drugs (Amendment No.2) (England, Wales and Scotland) Regulations 2013 (“the 2013 Regulations”) placed Sativex, which received marketing authorisation from the MHRA in 2010, in Part 1 of Schedule 4 to the 2001 Regulations. The Misuse of Drugs (Designation) (Amendment No. 2) (England, Wales and Scotland) Order 2013 placed Sativex in Part 2 to the Schedule to the Misuse of Drugs (Designation) Order 2001. Further, substances have previously been scheduled by reference to their form as “medicinal products”; see Part II, Schedule 4 of the 2001 Regulations prior to amendment by the Misuse of Drugs (Amendment No 2) (England, Wales and Scotland) Regulations 2012.
- 3.2 The Government has relied on its ability to make provisions in relation to “other different cases or circumstances” under section 31(1)(a) of the Misuse of Drugs Act 1971 (“the 1971 Act”). The form and purpose limitations reflect the need to ensure that access is available to patients where medically appropriate, whilst minimising the risks of misuse, harm and diversion. This is in the context of the particular and unusual challenges arising from the very high levels of unlawful recreational use of cannabis. Further information about the policy context is provided in paragraph 7.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.3 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England, Wales and Scotland.
- 4.2 The territorial application of this instrument is England, Wales and Scotland.
- 4.3 The Department of Health in Northern Ireland intends to make separate legislative provisions to mirror these amendments.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 The 2001 Regulations regulate legitimate access to drugs considered ‘dangerous or otherwise harmful’ and therefore controlled under Schedule 2 to the 1971 Act. Drugs so controlled are scheduled in one of five schedules under the 2001 Regulations. The schedule in which a drug is placed is based on an assessment of its medicinal or therapeutic usefulness, the need for legitimate access and the potential harm when misused. Scheduling dictates the extent to which it is lawful to import, export, produce, possess and supply. It also imposes requirements around the prescribing, record-keeping, labelling, destruction or safe custody of controlled drugs. By provisions made under the 1971 Act, the Secretary of State may also designate a drug as one to which section 7(4) of that Act applies. Once designated, drugs can only be made available for research or other special purposes or for use by practitioners, pharmacists and persons lawfully conducting retail pharmacy business under licence or other authority issued by the Home Office.
- 6.2 Currently, cannabis, cannabis resin, cannabidiol and cannabidiol derivatives (aside from dronabinol or its stereoisomers) are Class B drugs, listed in Schedule 1 to the 2001 Regulations and designated under the 2015 Designation Order. This instrument places a defined category of these controlled drugs (cannabis-based products for medicinal use in humans) in Part 2 of the Schedule to the 2015 Designation Order and Schedule 2 of the 2001 Regulations, with the effect that these products now become available for medicinal use without the need for a Home Office licence. This instrument also, by new Regulation 16A, imposes additional controls on the order and supply of these products for the purpose of administration (whether to humans or others) and maintains the prohibition on their use by smoking, except for research purposes. Further information on the definition of ‘cannabis-based product for medicinal use in humans’ and access limitations are provided in paragraph 7.
- 6.3 This instrument also amends the 2010 Regulations, which prescribe the fee payable where a licence is issued to engage in various activities in relation to controlled drugs (within the meaning of the 1971 Act). The instrument provides that no fee is payable where the Secretary of State determines that the fee should be waived. Licences issued by the Secretary of State provide, variously, that it will be lawful for person(s)

to import, export, produce, supply, offer to supply or possess controlled drugs in accordance with the terms and conditions of the licence.

7. Policy background

What is being done and why?

- 7.1 On 19 June 2018, the Home Secretary announced a two-part review of cannabis and its scheduling under the 2001 Regulations.

Part One

- 7.2 This was led by the UK Government's Chief Medical Adviser, Professor Dame Sally Davies and considered the available evidence of the therapeutic and medicinal benefits of cannabis based products. On 3 July 2018, the Chief Medical Adviser published her review and concluded that there was conclusive evidence of the therapeutic benefit of cannabis based medicinal products for certain medicinal conditions, and reasonable evidence of therapeutic benefit in several other medical conditions. The Chief Medical Adviser recommended that the whole class of cannabis-based medicinal products be moved out of Schedule 1 (including synthetic cannabinoids). The matter was referred to the Advisory Council on the Misuse of Drugs ("ACMD") for part-two of the review. The Chief Medical Adviser's advice is available at the following link:

<https://www.gov.uk/government/publications/cannabis-scheduling-review-part-1>

Part Two

- 7.3 The ACMD was then commissioned on the same day to provide short-term advice on whether cannabis (excluding Sativex), cannabis resin, cannabinol and cannabinol derivatives (not being dronabinol or its stereoisomers) and synthetic cannabinoids should be rescheduled under the 2001 Regulations and whether there were any further provisions which could be included in the 2001 Regulations to reduce the risks of harm and diversion for misuse. In addition, the ACMD was also asked to conduct a longer-term review within twelve months of the commission. The ACMD published its advice on 19 July 2018 and recommended that the Department of Health and Social Care ("DHSC") and the MHRA develop a clear definition of what constitutes a '*cannabis-derived medicinal product*', and that products meeting this definition should be available on prescription. The ACMD also recommended that additional frameworks for 'checks and balances' to maintain safe prescribing be developed. The ACMD was supportive of the Chief Medical Adviser's approach, with the exception of rescheduling synthetic cannabinoids, which the ACMD committed to review 'longer-term'. The ACMD advice and its full recommendation is available at the following link: <https://www.gov.uk/government/publications/advice-on-scheduling-of-cannabis-based-medicinal-products>
- 7.4 Having considered both reviews, the Home Secretary accepted the ACMD advice and undertook to reschedule '*cannabis-derived medicinal products*' under the 2001 Regulations.
- 7.5 DHSC, MHRA and the Home Office developed a definition of cannabis-based products for medicinal use (by reference to their form and purpose) as part of a package which also included additional regulatory access restrictions and non-legislative checks and balances. This was to ensure that access should be available to patients where medically appropriate, whilst minimising the risks of misuse, harm and

diversion. On 11 September 2018, the ACMD provided advice on the Government's draft proposals and issued eleven recommendations regarding the rescheduling of 'cannabis-derived medicinal products'. The further advice from the ACMD, including the eleven recommendations, is available at the following link: <https://www.gov.uk/government/publications/further-advice-on-scheduling-of-cannabis-derived-medicinal-products>

- 7.6 The Government considered all recommendations and, on 21 September 2018, the Home Secretary and the Secretary of State for Health and Social Care accepted all of them (although some aspects will be explored further in the context of the longer-term review rather than in this instrument). The Government response is available at the following link: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/742580/Final cleared ACMD response 21-09-18 RC.PDF](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/742580/Final_cleared_ACMD_response_21-09-18_RC.PDF)

The definition and rescheduling of 'cannabis-based product for medicinal use in humans'

- 7.7 The Government has been clear in its commitment to ensuring that cannabis-based products are available for medicinal use where clinically appropriate. However, it is not customary to reschedule a controlled drug which has not yet received a marketing authorisation from the MHRA or European Commission (such products are also known as an unlicensed medicine or 'special'). This is because controlled drugs are known to be dangerous or otherwise harmful, and the medicines licensing process provides assurances of a product's quality, safety and efficacy. In line with the UK Chief Medical Adviser's report, there is an imperative to reschedule cannabis-based products for medicinal use due to evidence of their therapeutic benefits. However, without the assurance of a marketing authorisation it is right that access to cannabis-based products for medicinal use is strictly controlled.
- 7.8 In line with the Government's commitment to ensuring that access is limited to cannabis-based medicinal products only, this instrument introduces a definition based on form and purpose, as well as composition, to make treatment options available with concomitant safeguards. There is a three-limb requirement to the definition of 'cannabis-based product for medicinal use in humans' which is defined as a preparation or other product, other than Sativex, which:
- a) *is or contains cannabis, cannabis resin, cannabidiol, or a cannabidiol derivative (not being Dronabinol or its stereoisomers);*
 - b) *is produced for medicinal use in humans; and*
 - c) *is a medicinal product or a substance or preparation for use as an ingredient of, or in the production of a medicinal product.*
- 7.9 Only products satisfying all three-limbs of this requirement are being rescheduled to Schedule 2 to the 2001 Regulations and de-designated from the 2015 Designation Order. The requirement for the product to be both "produced for medicinal use in humans", and to be either a medicinal product or an ingredient in a medicinal product, ensures that only products regulated as medicines and produced specifically for medicinal purposes are placed in Schedule 2. Any cannabis-based substance falling outside of this definition (for example, a cannabis-based product classified as a medicine but produced for recreational use) will remain a Schedule 1 drug to the 2001 Regulations and designated under the 2015 Designation Order.

- 7.10 The definition does not impact on the offence of cultivation of the cannabis plant under section 6(2) of the 1971 Act and requirement for a licence for cultivation under Regulation 12 of the 2001 Regulations to do so lawfully.

Access to cannabis-based products for medicinal use in humans

- 7.11 This section relates primarily to safety in prescribing, and to clinical trials.
- 7.12 The 2001 Regulations impose specific requirements to prevent the misuse of controlled drugs. Regulation 16 of the 2001 Regulations regulates the supply on prescription of Schedule 2 and Schedule 3 controlled drugs. Under the 2001 Regulations, Schedule 2 drugs can generally be prescribed by a practitioner, which includes a doctor, dentist, veterinary surgeon and veterinary practitioner. However, due to the concerns around the risks of harm, misuse and diversion of cannabis-based products for medicinal use, special measures of control have been included for the use, order and supply of these products for the purposes of administration (whether to human or animals). Whilst the evidence develops, the clinical expertise builds and the ACMD consider whether the definition needs to be refined as part of the longer-term review, there are only three access routes available for the order, supply and use of these products.
- 7.13 Firstly, if the product is unlicensed (i.e. without a marketing authorisation granted in accordance with the medicines legislation applicable in the UK), and is being ordered otherwise than for a clinical trial, the decision to order/prescribe the medicine can only be made by a doctor on the Specialist Register of the General Medical Council (“GMC”). The product that is therefore ordered/prescribed by them, or a doctor under their direction, will need to be supplied under long-standing arrangements for the supply of what are known, in healthcare settings, as “specials”. In the absence of the reassurance that the product licensing system provides about product safety, quality and efficacy, a greater burden of responsibility falls on the specialist doctor making the decision to prescribe. That doctor will need to look to other sources of reassurance and ultimately, it will be for the specialist doctor, making the decision to prescribe, to decide whether prescribing these products is in the best interest of the patient. The limitation on the decision to order/prescribe, to doctors on the Specialist Register of the GMC, replicates the principle used in the Interim Expert Panel on cannabis-based medicines. The Expert Panel had been put in place by the Home Secretary to allow for special licences to be issued where there was an exceptional clinical need.
- 7.14 Secondly, even if the product is unlicensed, it can still be used in clinical trials, in line with other Schedule 2 drugs provided that the necessary legislation surrounding clinical trials is also complied with. This is in line with the advice from the Chief Medical Adviser and the ACMD, to ensure that clinical trials for cannabis-based products for medicinal use can be undertaken. This will ensure that further evidence on cannabis-based products for medicinal use can be developed.
- 7.15 Thirdly, if a product is covered by a marketing authorisation (and so its quality, safety and efficacy have been established for certain indicated uses) it can then be prescribed by any practitioner, such as a General Practitioner, with the authority to do so under the 2001 Regulations. Once a medicinal product has received the necessary marketing authorisation, it ceases to be considered as a ‘special’ and can be prescribed in line with all other Schedule 2 controlled drugs.
- 7.16 A person cannot supply a cannabis-based product for medicinal use unless the product has been ordered lawfully. Pharmacies and persons administering these products will

need to be satisfied that one of the above three order routes has been complied with before lawfully dispensing or administering cannabis-based products for medicinal use. In practice, there will need to be an audit trail, accessible to the relevant enforcement authorities, giving the name of the specialist doctor making the decision to prescribe.

Cannabis-based products for medicinal use cannot be smoked

- 7.17 Due to the harms associated with smoking, the ACMD recommended ensuring that any prescription of cannabis-based products for medicinal use should not include smoking as a route of administration. There was also a concern that permitting smoking of cannabis-based products for medicinal use would make it significantly more difficult to enforce existing offences on the recreational use of cannabis. This instrument therefore continues to prohibit smoking of cannabis, by banning the administration of cannabis-based products for medicinal use in humans by smoking.

Waiving of fees

- 7.18 The 2010 Regulations prescribe fees payable where a licence is issued for individuals to engage in various activities in relation to controlled drugs (within the meaning of the 1971 Act). The regulations are amended to provide that the Secretary of State may waive the licence fee. In the exceptional event that families or patients are issued a Schedule 1 licence for treatment, this amendment will ensure that the Secretary of State can determine that no fee should be paid in that particular case, and so patients are not prevented from accessing appropriate medical treatment due to economic hardship.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

- 9.1 The Government intends to consolidate the 2001 Regulations in due course.

10. Consultation outcome

- 10.1 The Government has consulted its Chief Medical Adviser, the ACMD and the MHRA. The consultation with the ACMD fulfils the Governments duty under sections 7(7) and 31(3) of the 1971 Act.
- 10.2 A range of manufacturers and stakeholders were consulted informally to ensure the proposed policy, and definition of cannabis-based products for medicinal use, was workable in practice; and to explore possible supply chains for cannabis-based products prescribed as unlicensed medicines.
- 10.3 A full public consultation was not undertaken due to the need to ensure access to these products was made possible at the earliest opportunity. Re-scheduling cannabis-based products for medicinal use means that these products will be regulated under the controlled drugs and medicines regulatory regime.

11. Guidance

- 11.1 Guidance will be made available at the time this instrument comes into force. This will include interim clinical guidance from NHS England to support prescribers, and specific guidance from the Royal College of Physicians and the British Paediatric Neurology Association. The National Institute for Health and Care Excellence will be providing further clinical guidance, which is expected in October 2019. The MHRA will publish guidance detailing the controls on production and importation of special unlicensed medicines (including requirements for supply, distribution, storage, labelling and pharmacovigilance). The Home Office will issue guidance regarding Home Office licences for activities relating to cannabis-based products for medicinal use. Finally, guidance will also be issued to enforcement agencies to provide some assistance on the differentiation between the medicinal products and those used for recreational purposes.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies has been considered and is set out in the Government's impact assessment.
- 12.2 The impact on the public sector is also set out in the Government's impact assessment.
- 12.3 That full impact assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses as this measure is de-regulatory, however, a range of manufacturers and stakeholders were consulted informally to ensure the proposed policy and definition of cannabis-based products for medicinal use was workable in practice; and to explore possible supply chains for cannabis-based products prescribed as unlicensed medicines.

14. Monitoring & review

- 14.1 The ACMD will provide further advice by summer 2019 on the rescheduling of cannabis-based products for medicinal use and synthetic cannabinoids. Over the coming months, the Government will gather evidence and share with the ACMD on how the rescheduling and proposed controls have worked in practice. The Government aims to do so in sufficient time to inform the ACMD's final advice. The Government will consider this advice and will refine the approach where necessary.

15. Contact

- 15.1 Sara Anderson at the Home Office email: Sara.Anderson@homeoffice.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Gwen Nightingale and Katherine Merrifield at the Home Office can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 The Rt Hon Nick Hurd, Minister of State at the Home Office, can confirm that this Explanatory Memorandum meets the required standard.