WHC/2018/039

CYLCHLYTHYR IECHYD CYMRU

Dyddiad Cyhoeddi: 30 Hydref 2018

Llywodraeth Cymru
Welsh Government

STATWS: GWYBODAETH

CATEGORI: LLYTHYR GWEITHWYR IECHYD PROFFESIYNOL

Teitl: **Cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol**

Dyddiad dod i ben / Adolygu: Hydref 2019

I'w weithredu gan:
Prif Weithredwyr, Cyfarwyddwyr Meddygol a Phrif Fferyllwyr GIG Cymru

Angen gweithredu erbyn: *Angen gweithredu ar unwaith*

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Welsh Government

At: Brif Weithredwyr, Cyfarwyddwyr Meddygol, a Phrif Fferyllwyr

Cc: Arolygiaeth Gofal Iechyd Cymru

30 Hydref 2018

Annwyl Gydweithwyr,

Cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol

Ar 11 Hydref gosododd Llywodraeth y DU Reoliadau Camddefnyddio Cyffuriau (Diwygio) (Canabis a Ffioedd Trwyddedu) Cymru, Lloegr a'r Alban) 2018 sy'n diwygio Rheoliadau Camddefnyddio Cyffuriau 2001 i ailgofrestru rhai cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol. Daw rheoliadau diwygio 2018 i rym ar 1 Tachwedd 2018. Mae'r llythyr hwn yn rhoi canllawiau i glinigwyr sy'n gweithio yn y GIG a'r sector iechyd annibynnol yng Nghymru, yn dilyn y newid i'r rheoliadau.

Cefndir

Ym Mehefin 2018 lansiodd y Swyddfa Gartref adolygiad o ailgofrestru canabis at ddibenion meddygol. Ystyriodd Rhan 1 o'r adolygiad, a wnaed gan yr Athro Dame Sally Davies, Prif Gynghorydd Meddygol Llywodraeth y DU, fuddion therapiwtig a meddygol rhagnodi cynhyrchion sy'n seiliedig ar ganabis mewn pobl, a chasglodd fod tystiolaeth dda bod budd therapiwtig ar gyfer rhai cyflyrau meddygol, a thystiolaeth resymol mewn sawl cyflwr meddygol arall. Argymhellodd yr adolygiad fod cynhyrchion sy'n seiliedig ar ganabis yn cael eu symud allan o Atodlen 1 o'r Rheoliadau Camddefnyddio Cyffuriau.

Cynhaliodd y Cyngor Cynghorol ar Gamddefnyddio Cyffuriau (ACMD) ran dau o'r adolygiad. Yn dilyn y rhan gyntaf o'i adolygiad,[1] argymhellodd ACMD fod y *"cannabis-derived medicinal products of the appropriate standard"* yn cael eu symud allan o Atodlen 1 ac, ar yr amod y cytunir ar ddiffiniad addas o *cannabis product for medicinal use*, y dylent gael eu rhestru yn Atodlen 2 o'r Rheoliadau Camddefnyddio Cyffuriau. Byddai ailgofrestru cynhyrchion sy'n seiliedig ar ganabis fel cyffuriau a reolir o dan Atodlen 2 yn golygu y gallai rhai cynhyrchion sy'n seiliedig ar ganabis gael eu defnyddio at ddefnydd meddygol lle bo angen clinigol heb ei ddiwallu.

Mae Llywodraeth y DU wedi gosod gwelliant i'r Rheoliadau Camddefnyddio Cyffuriau a fydd yn ailgofrestru cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol, ac eithrio canabinoidau

[1]Disgwylir i ail ran adolygiad ACMD ddod i ben yn ystod haf 2019.

synthetig[2]. Yn ddarostyngedig i broses Seneddol, daw'r rheoliadau hyn i rym ar 1 Tachwedd 2018.

Rhagnodi cynhyrchion meddygol sy'n seiliedig ar ganabis

Diffiniad o gynhyrchion meddygol sy'n seiliedig ar ganabis

Yn rheoliadau diwygio 2018 mae Llywodraeth y DU wedi diffinio cynnyrch sy'n seiliedig ar ganabis at ddefnydd meddygol mewn pobl fel:

> *"A preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies[3] which—*
>
> *(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol[4] or its stereoisomers);*
> *(b) is produced for medicinal use in humans; and—*
> *(c) is—*
> *(i) a medicinal product, or*
> *(ii) a substance or preparation for use as an ingredient of, or in the preparation or manufacture of an ingredient of, a medicinal product."*

Pwy gaiff ragnodi cynhyrchion meddygol sy'n seiliedig ar ganabis?

Oherwydd y sylfaen dystiolaeth gyfyngedig a'u natur ddidrwydded, mae Llywodraeth y DU wedi cyfyngu ar ragnodi cynhyrchion sy'n seiliedig ar ganabis i'r clinigwyr hynny yn unig a restrir ar Gofrestr Arbenigwyr y Cyngor Meddygol Cyffredinol (GMC). Nodir y cyfyngiad hwn yn rheoliadau diwygio 2018.

Perthnasedd gweithdrefnau presennol wrth ragnodi a chyflenwi cynhyrchion meddygol sy'n seiliedig ar ganabis

Yn y DU, bydd yr holl gynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol (a restrir ar hyn o bryd yn atodlen A o'r Rheoliadau Camddefnyddio Cyffuriau) yn **feddyginiaethau didrwydded.** Darperir gwybodaeth bellach am drwyddedu mewn atodiad i'r llythyr hwn. Yn ogystal, disgwylir na ddylai meddygon ragnodi ond o fewn eu maes ymarfer arbenigol.

Fel gydag unrhyw feddyginiaethau didrwydded, rhaid i gynhyrchion sy'n seiliedig ar ganabis gael eu rhagnodi ar sail claf a enwir. Rhaid i weithdrefnau ynghylch rhagnodi meddyginiaethau didrwydded gael eu dilyn; rhaid i drefniadau fod yn eu lle i sicrhau bod modd archwilio'r holl waith rhagnodi yn achos cynhyrchion sy'n seiliedig ar ganabis. Fel cyffuriau a reolir o dan Atodlen 2, rhaid i ragnodi cynhyrchion didrwydded sy'n seiliedig ar ganabis hefyd ddilyn gweithdrefnau ar gyfer rhagnodi cyffuriau a reolir.

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[2] Mae ailgofrestru yn gymwys i ganabis a pharatoadau canabis yn unig (megis deunydd a dynnir o ganabis yn ogystal â chanabinoidau a ynysir oddi wrth ganabis). Nid yw'n cynnwys fersiynau synthetig o ganabinoidau sy'n digwydd yn naturiol (e.e. marinol/dronabinol) neu unrhyw ganabinoidau nad ydynt yn naturiol a geir trwy synthesis cemegol (e.e. nabilone).

[3] *i.e. Sativex*

[4] *In the United Kingdom, "dronabinol" does not refer to a tetrahydro derivative of a plant based cannabinol derivative, or to 3-alkyl homologues of such cannabinol derivatives or their tetrahydro derivatives, but instead to a synthetic product that is not plant based*

Canllawiau proffesiynol perthnasol

Rhaid i unrhyw benderfyniad i ragnodi cynnyrch sy'n seiliedig ar ganabis roi sylw i ganllawiau GMC a'r Asiantaeth Rheoleiddio Meddyginiaethau a Chynhyrchion Gofal Iechyd (MHRA) ynghylch rhagnodi meddyginiaethau didrwydded, yn ogystal â'r gweithdrefnau perthnasol ar gyfer rhagnodi cyffuriau a reolir a meddyginiaethau didrwydded sy'n bodoli yn y bwrdd iechyd, ymddiriedolaeth y GIG neu ddarparwr gofal iechyd annibynnol.

Goruchwylio sefydliadol

Fel mater o arfer da, byddem yn disgwyl y bydd unrhyw benderfyniad i ragnodi cynnyrch sy'n seiliedig ar ganabis fod wedi cael ei wneud ar ôl trafod yr achos perthnasol, rhwng y meddyg sy'n rhagnodi a chymheiriad y cynhwysir ei enw yn yr un gofrestr arbenigwyr a gedwir gan y GMC. Yng nghyrff y GIG, dylid sefydlu trefniadau priodol i sicrhau bod pob penderfyniad i ragnodi yn cael ei gymeradwyo gan Gyfarwyddwr Meddygol y sefydliad neu Uwch-Glinigydd (Uwch-Glinigwyr) a enwebir gan y Cyfarwyddwr Meddygol. Dylai trafodaethau rhwng cymheiriaid a chymeradwyaeth y Cyfarwyddwr Meddygol gael eu dogfennu'n briodol.

Mynegiannau therapiwtig ar gyfer cynhyrchion sy'n seiliedig ar ganabis

Dylai cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol gael eu rhagnodi yn unig ar gyfer mynegiannau:

1. Lle bo tystiolaeth glir o fudd;
2. Lle na ellir diwallu angen clinigol claf trwy feddyginiaeth drwyddedig; a
3. Lle y mae pob opsiwn ar gyfer triniaeth sefydledig wedi'i ddefnyddio.

Pan gaiff cynnyrch sy'n seiliedig ar ganabis eu rhagnodi at ddefnydd meddygol, dylid cytuno ar nodau clir o ran y driniaeth cyn i'r driniaeth ddechrau. Dylai trefniadau fod yn eu lle ar gyfer adolygu'n rheolaidd a yw'r rhagnodi yn cyd-fynd â nodau'r driniaeth. Dylai'r driniaeth ddod i ben os nad yw'r nodau hynny'n cael eu cyflawni'n ddigonol.

Dewis cynhyrchion sy'n seiliedig ar ganabis at ddibenion rhagnodi

Disgwylir i feddygon rhagnodi yn unig lle y gallant fod yn sicr am eu cynnwys a'u hansawdd. Er enghraifft, ni ddylai cynhyrchion gael eu rhagnodi lle mae faint o ganabinoidau sydd yn y cynnyrch naill ai yn anhysbys, yn ansicr neu heb ei ddatgan ar label y cynnyrch. Byddai disgwyl i gynhyrchion fodloni'r gofynion a nodir yng Nghanllawiau MHRA ar Gyffuriau Didrwydded.

Cyn rhagnodi cynnyrch sy'n seiliedig ar ganabis, dylai'r rhagnodwr drafod dod o hyd i gynnyrch addas sy'n bodloni'r gofynion a nodir gan yr MHRA gydag adran fferylliaeth y sefydliad. Dylai'r drafodaeth hon gynnwys Prif Fferyllydd y sefydliad neu Uwch-Fferyllydd a enwebir gan y Prif Fferyllydd. Dylai adrannau fferyllol ddilyn arferion proffesiynol wrth gaffael a chyflenwi cynhyrchion sy'n seiliedig ar ganabis yn unol â Chanllawiau Proffesiynol y Gymdeithas Fferyllol Frenhinol (RPS) ar gyfer Caffael a Chyflenwi Cyffuriau Didrwydded.

Yn yr un modd, disgwylir i glinigwyr a fferyllwyr sy'n gweithio yn y sector annibynnol ddilyn prosesau ar gyfer rhagnodi a chyflenwi cyffuriau didrwydded sy'n rhoi sylw i ganllawiau GMC, RPS ac MHRA.

Canllawiau Clinigol

I gefnogi penderfyniadau rhagnodi clinigwyr arbenigol, bydd y Sefydliad Cenedlaethol dros Ragoriaeth mewn Iechyd a Gofal (NICE) yn cynhyrchu canllawiau clinigol ar ragnodi cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol. Disgwylir y bydd y canllawiau hyn ar gael erbyn Hydref 2019.

Yn y cyfamser, bydd y Gymdeithas Niwroleg Baediatrig Prydain (BPNA) yn datblygu cyngor clinigol ar ddefnyddio cynhyrchion sy'n seiliedig ar ganabis mewn epilepsi paediatrig. Bydd Coleg Brenhinol y Meddygon (RCP) yn datblygu cyngor ychwanegol ynghylch rhagnodi ar gyfer cyfogi ac awydd cyfogi a phoen cronig a ddaw yn sgil cemotherapi ac sydd, o ganlyniad, yn anodd eu trin.

Gwyliadwriaeth ffarmacolegol

Ym mhob achos pan gaiff cynhyrchion sy'n seiliedig ar ganabis at ddefnydd meddygol eu rhagnodi, dylai clinigwyr sy'n trin cleifion gadw asesiad manwl o fesurau clinigol a mesurau canlyniadau cleifion i gefnogi diogelwch cleifion a dealltwriaeth fwy hirdymor o effeithiolrwydd cynhyrchion sy'n seiliedig ar ganabis. Bydd hyn yn cynnwys rhoi gwybod am **bob** adwaith andwyol i'r cynnyrch (boed trwyddedig neu ddidrwydded) i Gynllun Cerdyn Melyn MHRA.

Cyfrifoldebau Swyddogion Atebol Cyffuriau a Reolir

Bydd cynhyrchion sy'n seiliedig ar ganabis yn gyffuriau a reolir o dan atodlen 2. Mae gan Swyddogion Atebol Cyffuriau a Reolir (CDAOs) gyfrifoldeb statudol dros sicrhau bod cyffuriau a reolir yn cael eu rheoli a'u defnyddio yn ddiogel yn eu sefydliad ac, yn achos CDAOs bwrdd iechyd lleol, yn sefydliadau a chan weithwyr proffesiynol y mae eu bwrdd iechyd lleol yn gyfrifol amdanynt. Rhaid i CDAOs sicrhau (a derbyn sicrwydd) bod gweithdrefnau yn bodoli i ddangos hyn. Mae hyn yn cynnwys dyletswydd i fonitro'r ffordd y mae cyffuriau a reolir yn cael eu rhagnodi, eu cyflenwi a'u gweinyddu. Disgwylir y bydd CDAOs yn ystyried a fydd angen camau llywodraethu ychwanegol i sicrhau bod cynhyrchion sy'n seiliedig ar ganabis yn cael eu cyflwyno'n ddiogel at ddefnydd meddygol mewn ymarfer clinigol.

Yn gywir

DR FRANK ATHERTON
Prif Swyddog Meddygol/
Cyfarwyddwr Meddygol, GIG Cymru

Andrew Evans
Prif Swyddog Fferyllol

Atgynhyrchir y testun fel y cafodd ei ddrafftio gan y Swyddfa Gartref

Annex I - Types of Products

Cannabis has many active chemical constituents and two of these constituents, tetrahydrocannabinol (THC) and cannabidiol (CBD) have been investigated the most in respect of their medicinal value. THC is the major psychoactive constituent of cannabis and is considered responsible for giving so called “highs” to users of cannabis. CBD on the other hand, is not psychoactive.

Products falling within Schedule 2 will contain varying quantities and ratios of THC and CBD and may be available in a range of pharmaceutical forms, including as the herbal material or as extracts formulated for example as oils and capsules. Manufacturers should adhere to Good Manufacturing Practice. "Pure CBD" is not a controlled drug for the purposes of the 1971 Misuse of Drugs Act.

There is also a wide range of other cannabis products available on the internet and in some commercial outlets such as health food outlets and from cannabis *‘dispensaries*’ internationally. These products are of unknown quality and contain CBD and THC in varying quantities and proportions. In the opinion of the Home Office (see its guidance note here), any CBD product that contains any amount of THC will be a controlled drug within the meaning of the 1971 Misuse of Drugs Act, except under very specific circumstances. Therefore using cannabis-based products that do not meet the official definition of a cannabis-based product for medicinal use (such as home-grown or street cannabis) for therapeutic benefit is illegal and potentially dangerous and patients should be reminded of this. The evidence that cannabis and some of its constituents can be addictive and harmful is well known and is not disputed by recent science.

The health harms of smoking are clear, therefore the regulations prohibit the self-administration of a cannabis-based product for medicinal use in humans by way of smoking other than for research purposes, and patients should be informed of the health risks associated with such use.

Current Licensing

Sativex® - (cannabis extracts containing THC and CBD) is the only licensed cannabis based medicinal product that is available in the UK. It has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA) as a treatment for spasticity in multiple sclerosis since 2010. Sativex is listed under Schedule 4 of the Misuse of Drugs Regulations 2001 at present. However Sativex® is currently subject to a NICE ‘do not do’ recommendation: *Do not offer Sativex to treat spasticity in people with MS because it is not a cost effective treatment.*

To date, the MHRA has licensed **no** other cannabis products as medicines. However, nabilone, a synthetic, non-natural cannabinoid, is licenced in the UK for use in treatment resistant nausea and vomiting caused by chemotherapy; dronabinol, a synthetic nature-identical, version of THC is listed under Schedule 2 of the Misuse of Drugs Regulations 2001, but it does not have a Market Authorisation from the MHRA in the UK, although it is available internationally.

Manufacture, importation, distribution and supply

MHRA guidance sets out the requirements for the manufacture, import, distribution and supply of cannabis-based products for medicinal use. This applies the same principles that apply to other unlicensed medicines, and manufacturers and importers of these products will require the necessary licences issued by the MHRA.

Department of Health & Social Care

NHS England 70 YEARS OF THE NHS 1948 - 2018

Scottish Government Riaghaltas na h-Alba gov.scot

Department of Health | An Roinn Sláinte Männystrie O Poustie

Llywodraeth Cymru Welsh Government

Tuesday 20th November 2018
Gateway Publications clearance: 08652

Dear Colleagues

Supplementary information on cannabis-based products for medicinal use

Following the letter issued on the 31st of October 2018, this supplementary letter provides further guidance to clinicians and organisations following the re-scheduling of cannabis-based products for medicinal use on November 1st 2018.

Clinical Guidance

We have been asked to clarify the status of the clinical guidance issued.

As highlighted previously, the National Institute for Health and Care Excellence (NICE) has been asked by the Department of Health and Social Care to produce a clinical guideline on the prescribing of cannabis-based products for medicinal use in humans. This guideline is expected by October 2019 at the latest.

The interim clinical guidance published by the British Paediatric Neurology Association (BPNA) on the use of cannabis-based products for medicinal use in children and young people with epilepsy and the Royal College of Physicians (RCP) guidance around prescribing of cannabis-based products for medicinal use in chemotherapy induced nausea and vomiting, chronic pain and pain in palliative care patients is based on the best available clinical evidence. NHS England have also asked the Association of British Neurologists (ABN) to provide interim guidance on the use of cannabis-based products for medicinal use in adult neurological conditions, including Multiple Sclerosis (MS).

Whilst this interim guidance is available to support specialist doctors on the Specialist Register of the General Medical Council (GMC) in deciding whether to prescribe cannabis-based products for medicinal use in a limited number of conditions, this does not remove or replace the clinical

discretion of the prescriber in accordance with their professional duties. We expect clinicians to work with their individual patients or their carers (where appropriate) to agree the best treatment, taking into account the clinical evidence base, GMC prescribing guidance on licensed, off label and unlicensed medicines, and local medicines governance systems. This is in line with normal clinical practice.

A set of clinical frequently asked questions (FAQs) is currently being prepared to provide further support to prescribers; once available these will be published here. In the meantime, clinicians should discuss any queries around prescriptions with their local hospital Chief Pharmacist/Director of Pharmacy in the first instance.

Synthetic Cannabinoids

Cannabis-based products for medicinal use can be divided into those that are naturally occurring in the cannabis plant and those that are synthetic. A summary of naturally occurring products are provided in annex 1.

We would also like to provide further clarification in relation to synthetic cannabinoids for medicinal use. This clarification is intended to help clinicians understand the distinctions between the different types of synthetic cannabinoids and to raise awareness that two synthetic cannabinoids (Dronabinol and Nabilone) remain available for prescribing and have not been affected by the recent legislative change.

There are three main groups of chemical compounds that fall within the broad category of 'synthetic cannabinoids'.

1. Synthetic compounds which are identical in structure to naturally occurring cannabinoids such as delta-9-tetrahydrocannabinol (THC) e.g. Dronabinol.

2. Synthetic compounds structurally *related* to naturally occurring cannabinoids that have been developed to mimic naturally occurring cannabinoids such as THC e.g. Nabilone.

3. Synthetic compounds not structurally related to naturally occurring cannabinoids but which bind to cannabinoid receptors in the body.

With respect to group 1 compounds, Dronabinol has been developed as a medicinal product. In addition, in group 2, Nabilone has also been developed for medicinal use and is available as a licensed medicinal product. See Annex 2 for further details.

Group 3 synthetic compounds not structurally related to naturally- occurring cannabinoids but which bind to cannabinoid receptors in the body are not available as licensed medicinal products. Many of the compounds in group 3 have frequently been found in illicit street products referred to by the street names of Spice and Black Mamba, and are predominantly new psychoactive substances (NPS). There is clear evidence of significant harm and several deaths associated with their illicit use.

The Advisory Council on the Misuse of Drugs (ACMD) has particular concerns with compounds falling within group 3 and others within group 2, with the exception of Nabilone, and is of the view that further research into this complex group of diverse substances is important, given the associated potency and harms. The ACMD stated that they needed further time to consider and

consult on the unintended consequences of the potential rescheduling of these products. Therefore, all synthetic cannabinoid compounds, unless authorised for medicinal use, will remain in Schedule 1 of the Misuse of Drugs Regulations 2001 (and Misuse of Drugs (Northern Ireland) Regulations 2002) at least until the full ACMD review is concluded; this is due to be published by July 2019. Consideration may then be given as to whether to re-schedule any further synthetic cannabinoid compounds for medicinal use.

As it currently stands: Compounds in group 1, such as Dronabinol, can lawfully be prescribed. Only compounds in group 2 that have been rescheduled individually under the Misuse of Drugs Regulations 2001 can prescribed e.g. Nabilone. None of the synthetic compounds in group 3 are available for prescribing.

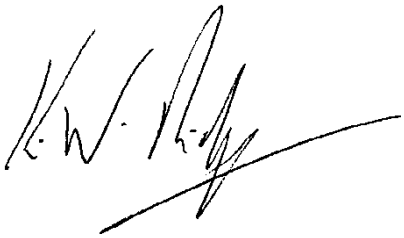
Further information can be found here[1] and on the current classifications of cannabis products for medicinal use in the annexes to this letter.

This letter has been agreed by Chief Medical Officers and Chief Pharmaceutical Officers across the United Kingdom.

Yours sincerely,

Professor Dame Sally C Davies
Chief Medical Officer, England

Professor Stephen Powis
National Medical Director
NHS England



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[1] https://www.england.nhs.uk/medicines/support-for-prescribers/cannabis-based-products-for-medicinal-use/
https://gov.wales/docs/dhss/publications/whc2018-039en.pdf
https://www.health-ni.gov.uk/sites/default/files/publications/health/hss-md-28-2018.pdf
https://www.sehd.scot.nhs.uk/cmo/CMO(2018)15.pdf

Dr Michael McBride
Chief Medical Officer,
Northern Ireland

Dr Mark Timoney
Chief Pharmaceutical
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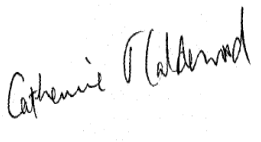

Dr Catherine Calderwood
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Dr Rose Marie Parr
Chief Pharmaceutical Officer,
Scottish Government

Annex 1

Summary of Naturally Occurring Cannabis-Based Products for Medicinal Use

Product	Constituents	Licensing	Indication	Controlled Drug Status	Which clinicians can prescribe?	Commissioning arrangements in England only[2]
Cannabis-based products for medicinal use as defined by the change in regulations on 1st November 2018						
Cannabis-based products for medicinal use[3] e.g. Tilray and Bedrocan products that were supplied under a Home Office (HO) licence.	A range of preparations containing delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD) with differing percentages of the active constituents. The product to be specified by brand/supplier; cannabis strain and content of THC/CBD (and ratio of THC/CBD where relevant), as appropriate.	**Unlicensed specials** Suppliers should comply with MHRA guidance and Good Manufacturing Practice standards.	Available on a named patient basis for indications where there is clear published evidence of benefit or UK Guidelines and in patients where there is a clinical need which cannot be met by a licensed medicine and where established treatment options have been exhausted.	Schedule 2	Specialist doctors on the GMC specialist register only can take the decision to prescribe.	Commissioning will depend on the indication that these products are prescribed for. Trusts will need to pick up the costs for named patients until normal commissioning processes can be defined.
Cannabis-based products already available for medicinal use in the UK prior to 1st November 2018						
Epidiolex® oral solution	Cannabidiol (CBD) isolated in pure form from Cannabis.	**Unlicensed in the UK.**	Approved by the US Food and Drug Administration (FDA) for Lennox-Gastaut Syndrome or Dravet Syndrome in patients 2 years of age and older.	Not a controlled drug	No restrictions on prescribing however likely to be specialist prescribing due to the nature of the proposed indications.	Lennox-Gastaut Syndrome and Dravet Syndrome is commissioned by NHS England Specialised Commissioning. Not routinely commissioned currently but this will be tariff excluded from April 2019 subject to a consultation.

[2] Arrangements for the routine availability of medicines will differ in Scotland, Wales and Northern Ireland and clinicians should confirm specific arrangements in line with local protocols.

[3] Note: Other cannabis-based products are on the market, often sold as food supplements. There is no assurance they have been manufactured to Good Manufacturing Practice standards using pharmaceutical grade ingredients or that they have consistent levels of ingredients between batches. These products should not be prescribed.

			Currently going through licensing in Europe. The marketing authorisation for the UK may further define who should prescribe**.**		Currently unlicensed so accessed on a named patient basis.	Currently going through normal commissioning processes and a NICE Technology Appraisal due for publication in November 2019. Early Access Programme available – speak to your local hospital Chief Pharmacist.
Sativex® (nabiximols) oromucosal spray	Extracts from two strains of cannabis with standardised content of the active constituents delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).	**Licensed**	Symptom improvement in adult patients with moderate to severe spasticity due to Multiple Sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	Schedule 4	Must be initiated and supervised by a doctor with specialist expertise in treating MS patients as defined by the Marketing Authorisation.	Sativex® falls under the commissioning responsibility of Clinical Commissioning Groups (CCGs). However, it is currently not recommended by NICE.

Annex 2

Summary of Synthetic Cannabis-Based Products for Medicinal Use

Product	Constituents	Licensing	Indication	Controlled Drug Status	Which clinicians can prescribe?	Commissioning arrangements in England only[4]
Synthetic cannabis-based products already available for medicinal use in the UK prior to 1st November 2018						
Dronabinol capsule	Synthetic structurally-identical form of delta-9-tetrahydrocannabinol (THC) (Group 1).	**Unlicensed in the UK.**	It has been approved by the US Food and Drug Administration (FDA) to treat loss of appetite in people with AIDS, and to treat severe nausea and vomiting caused by cancer chemotherapy in patients with inadequate response to conventional antiemetic treatments.	Schedule 2	No restrictions on prescribing. Unlicensed so accessed on a named patient basis.	Chemotherapy and HIV services are commissioned by NHS England. This would be in tariff but as an unlicensed medicine it would not be routinely commissioned. Trusts would pick up costs.
Nabilone capsule	Synthetic non-natural cannabinoid that mimics delta-9-tetrahydrocannabinol (THC) (Group 2).	**Licensed**	Nausea and vomiting caused by chemotherapy, unresponsive to conventional antiemetics.	Schedule 2	No restrictions on prescribing. Summary of product characteristics states: Preferably administered in a Hospital setting, under close supervision. GP's may prescribe once initiated.	NHS England is responsible for commissioning chemotherapy and associated supportive drugs if given as part of a chemotherapy regimen. If used outside an agreed regimen it is considered in tariff.

4 Arrangements for the routine availability of medicines will differ in Scotland, Wales and Northern Ireland and clinicians should confirm specific arrangements in line with local protocols.