

Area Drug and Therapeutics Committee

MEDICINAL CANNABIS: INFORMATION FOR PRESCRIBERS



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Introduction

With the change in regulations which came into effect on 1st November 2018 to facilitate the prescribing of cannabis-based medicines in the UK, there has been substantial media coverage and enquiries from patients. This information sheet is intended to provide a summary of information for clinicians in NHSGG&C. A separate information sheet is available for patients [here](#).

Summary of guidance for specific medicinal cannabis preparations

Preparation	Indications	How to request	Prescription requirements and other considerations
Epidyolex®	Dravet Syndrome, Lennox-Gastaut Syndrome (LGS)	Licensed Medicine accepted for use by the Scottish Medicines Consortium (SMC) and available for use in accordance with local guidance.	Schedule 5: Controlled drug storage, prescription writing and record keeping requirements do not apply. Invoices should be retained for 2 years.
Nabilone	Refractory chemotherapy-induced nausea and vomiting	No additional forms required.	Schedule 2: Controlled Drug prescribing, storage, supply and recording requirements apply
Sativex®	Spasticity associated with multiple sclerosis	Individual Patient Treatment Request (IPTR) to be completed and approved prior to prescribing	Schedule 4: No special prescribing or controlled drug storage requirements, but recording requirements still apply.

What are the legislation changes?

Since 2018, cannabis-based products for medicinal use come under Schedule 2 of the Misuse of Drugs Regulations 2001. A summary of the changes that came into effect at that time is covered in the [CMO letter](#) (31st Oct 2018).

In July 2020, Epidyolex® moved to Schedule 5 of the Misuse of Drugs Regulations 2001, effectively removing restrictions around prescription writing, storage and record keeping.

Supplementary information on cannabis-based products for medicinal use was published on 20th November 2018 by the Scottish Government and can be accessed [here](#).

Other cannabis products will remain in Schedule 1 and supply and possession remains illegal without a Home Office licence. The status of cannabis under the Misuse of Drugs Act 1971 and modifications as a Class B drug have not changed, therefore penalties for illicit (non-medicinal) use, unauthorised supply and possession remain unchanged.

A set of clinical frequently asked questions (FAQs) prepared by NHS England with input from the Scottish Government is published [here](#).

The MHRA has issued [guidance on supply, manufacture, importation and distribution](#) of unlicensed cannabis-based products for medicinal use in humans following rescheduling.

Who can prescribe medicinal cannabis?

Only consultant clinicians working within their own area of expertise should make a decision to prescribe medicinal cannabis. Any decision to prescribe will then have to go through local approval processes (see later in this guidance) before it can be supplied to a patient. The expectation is that GPs will not be involved in the initiation or ongoing prescribing of any medicinal cannabis products at this time. In addition, any dispensing of medicinal cannabis preparations will be via hospital pharmacy departments.

What conditions can medicinal cannabis be prescribed for?

Medicinal cannabis should only be considered:

1. where there is clear published evidence of benefit or there are existing UK guidelines
AND
2. where there is a clinical need which cannot be met by licensed medicines or where other treatment options have been exhausted.

Currently, there is only conclusive evidence of therapeutic benefit in the following conditions:

- Rare forms of epilepsy in children and young adults (Dravet Syndrome and Lennox-Gastaut Syndrome (LGS)) and the British Paediatric Neurology Association have published [clinical guidance](#) to support this.
- Chemotherapy-induced nausea and vomiting unresponsive to other treatment options, where antiemetics should continue to be prescribed in accordance with the [WOSCAN guidelines](#).
- Spasticity due to multiple sclerosis.

The use of medicinal cannabis for other conditions, including use for pain, is not considered to have a robust enough evidence base currently and are not recommended. The Royal College of Physicians have provided [recommendations](#) outlining this.

What medicinal cannabis products can be prescribed?

Only cannabis-based products which meet the UK Government criteria for medicinal use in humans can be prescribed. Currently, these criteria only cover a small number of known unlicensed and licensed cannabis-based or synthetic cannabinoid products.

- Epidyolex[®] is a licensed medicinal cannabis preparation indicated for use in combination with clobazam in Dravet Syndrome and LGS. It is accepted for use within NHSScotland for these licensed indications by the Scottish Medicines Consortium (SMC) and included in the GGC Adult and Paediatric Medicines Formularies.
- Sativex[®] oromucosal spray is a licensed cannabinoid-based product specifically for moderate to severe spasticity due to multiple sclerosis. However, it is not recommended for use by the Scottish Medicines Consortium (SMC) following a non-submission. The change in regulatory status of medicinal cannabis therefore does not impact on the access to Sativex[®].
- Nabilone is a synthetic cannabinoid which is licensed for the control of nausea and vomiting, caused by chemotherapeutic agents used in the treatment of cancer, in adult patients who have failed to respond adequately to conventional antiemetic treatments.

- For further information about other medicinal-cannabis products, please refer to the [supplementary information from the Scottish Government](#) from 20th November 2018. These products are considered to be unlicensed medicines and access would be in accordance with existing policies for unlicensed medicines.

It is likely that the number of available preparations that meet the requirements set by the UK Government will increase in the future.

Over the counter CBD oils which are sold legally do not meet the requirements of UK Government criteria for medicinal use in humans and should not be prescribed.

Synthetic cannabis products, other than those specifically licensed as a medicine (e.g. nabilone) are not available for prescribing.

How are requests to prescribe medicinal cannabis made?

The documentation used to make the request to initiate medicinal cannabis will depend on which product and indication it is being sought for:

- Epidyolex® for Dravet Syndrome or LGS can be prescribed, within the licensed indications, without any additional documentation by relevant specialist prescribers in accordance with local guidance. It is expected that all requests will be within either the Regional Services or Women and Children's directorate.
- Requests for Sativex® for spasticity related to multiple sclerosis (MS) are currently via an Individual Patient Treatment Request ([Form IPTR3](#)) which should then be submitted for consideration to the relevant Chief of Medicine. It is expected that all requests will be within the Regional Services directorate.
- Use of Sativex® for indications other than spasticity related to MS are unlicensed and any requests are via an Unlicensed Medicine Form ([Form ULM1](#)) which should then be submitted for consideration to the relevant Chief of Medicine.
- Requests for other unlicensed medicinal cannabis products require an Unlicensed Medicine Form ([Form ULM1](#)) which should then be submitted for consideration to the relevant Chief of Medicine

How should medicinal cannabis be prescribed?

To prevent confusion with medicinal cannabis products, it is currently preferred that these products are prescribed by brand name where possible.

The prescribing requirements will depend on the medicinal cannabis product being prescribed:

- Epidyolex® is a licensed Schedule 5 controlled drug. This means there are no specific prescription requirements.
- Sativex® oromucosal spray is not subject to these prescribing requirements as its legal classification is a schedule 4 controlled substance.
- Nabilone and other medicinal cannabis preparations that are suitable for prescribing are classed as schedule 2 controlled drugs and are subject to [certain legal requirements](#) for their prescribing, supply and administration.

Access to medicinal cannabis from private healthcare providers

Private healthcare facilities offering the prescription of medicinal cannabis products are available within Scotland. The expectation is that these private healthcare providers will abide by the same national guidance and legislation as summarised in this document. In accordance with principles outlined by the Scottish Government¹ care provided by the NHSGG&C and private care should be delivered separately with clear separation in legal status, liability and accountability between the NHSGG&C and private healthcare providers. Therefore, it must be made clear to any patient making use of these private facilities that any recommended or prescribed treatments must remain the responsibility of the private healthcare provider and would not be subsidised by NHSGG&C funding.

Consultant physicians in NHSGG&C who are considering referring patients to such private healthcare providers are asked in the first instance to discuss the matter with the relevant Chief of Medicine prior to any referral being made. This is to allow for consideration of governance arrangements.

Where can patients get more information?

The GGC Medicines website now has a patient information page specifically for medicinal cannabis which currently links to resources from NHS England along with clarifying aspects of the guidance for the NHS in Scotland.

The page can be accessed via this link: www.ggcmedicines.org.uk/medicinal-cannabis/

Written by Medicines Information Service & the Controlled Drug Governance Team
Approved by NHSGG&C Area Drug & Therapeutics Committee – April 2021

¹ Scottish Government. Arrangements for NHS patients receiving healthcare services through private healthcare arrangements. SGHD/CMO(2009)3. Published 25/03/2009 and accessed via www.sehd.scot.nhs.uk

If you require any further information or advice please contact either:

Medicines Information (Telephone: 0141 201 3227 or E-mail: Medinfo@ggc.scot.nhs.uk)

Controlled Drugs Governance Team (Telephone: 0141 201 6033 E-mail: CDGovernance@ggc.scot.nhs.uk)