Area Drug and Therapeutics Committee

MEDICINAL CANNABIS:
INFORMATION FOR PRESCRIBERS

Last Updated: 6th December 2018

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
Epidiolex®	Dravet Syndrome, Lennox-Gastaut Syndrome (LGS)	Unlicensed Medicine Form to be completed and approved by Chief of Medicine prior to prescribing	No specific prescription requirements
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?

Cannabis-based products for medicinal use have now moved out of Schedule 1 and into Schedule 2 of the Misuse of Drugs Regulations 2001. A summary of the changes is covered in the CMO letter (31st Oct 2018).

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) is currently being prepared by NHS England with input from the Scottish Government and will be published here in due course.

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

If you require any further information or advice please contact either:
Medicines Information (Telephone: 0141 211 4407 or E-mail: Medinfo@ggc.scot.nhs.uk)
Controlled Drugs Governance Team (Telephone: 0141 201 6033 E-mail: CDGovernance@ggc.scot.nhs.uk)

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 memo) 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 unlicensed 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.

- Epidiolex® is a medicinal cannabis preparation intended for use in Dravet Syndrome and LGS. It is currently unlicensed in the UK, though is currently going through the regulatory process.
- 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.

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:

- Requests for Epidiolex® for Dravet Syndrome or LGS are via an Unlicensed Medicine Form (Form ULM1) which should then be submitted for consideration to the relevant Chief of Medicine. 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.

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:

- Epidiolex® is currently unlicensed, but as it is not a controlled drug 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.

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 – December 2018

If you require any further information or advice please contact either:
Medicines Information (Telephone: 0141 211 4407 or E-mail: Medinfo@ggc.scot.nhs.uk)
Controlled Drugs Governance Team (Telephone: 0141 201 6033 E-mail: CDGovernance@ggc.scot.nhs.uk)