

Cannabis for Medical Use

Information for Patients and healthcare professionals.

- **Introduction**

The following information is for healthcare professionals, patients and others who are interested in finding out more about cannabis for medical use. It will discuss current and proposed access to potential cannabis treatment and describe the legal and policy status of cannabis. It also describes the Minister for Health's role in relation to access to cannabis for medical use, as provided for in the Misuse of Drugs Acts 1977-2016 and in line with expert clinical and scientific advice.

Cannabis and cannabis-based products which do not have a marketing authorisation are not medicines as defined under national and European legislation. As such, they are not subject to the same rigorous safety, quality and efficacy standards that are in place for medicines, nor are the producers subject to the same responsibilities as the marketing authorisation holders for authorised medicines.

This document refers only to cannabis for medical use. Other matters related to cannabis including recreational use, decriminalisation, non-medical research, manufacturing, growing/producing cannabis or any other cannabis-related matters should be considered separate and distinct from the information below.

- **Background and Policy Context to use of cannabis for medical purposes in Ireland**

There is considerable public interest in the use of cannabis for medical purposes. While the medical potential of cannabis is clearly of interest and potentially promising, the quality of the evidence reported so far is limited.

[A Health Products Regulatory Authority \(HPRA\) review in 2017](#) concluded that the available scientific evidence found, at best, a moderate benefit for cannabis in a small number of medical conditions.

- **Differences between the main active components of cannabis - THC and CBD**

The two active components of cannabis that are of current medical interest are tetrahydrocannabinol (THC) and cannabidiol (CBD).

THC

THC is the main psychoactive constituent of cannabis. Under the Misuse of Drugs legislation, products containing THC are strictly controlled and possession is unlawful, except under Ministerial licence.

CBD

CBD is also derived from cannabis; however, as it is not psychoactive, it is not controlled under the Misuse of Drugs legislation. Products containing only CBD therefore do not require a Ministerial licence for use.

- **Legal and policy position on access to cannabis for medical use**

The Misuse of Drugs Acts 1977 to 2016, and enabling Regulations, set out the controls and restrictions that apply to cannabis in Ireland.

Under the Misuse of Drugs Regulations 2017, cannabis and products or preparations extracted from the cannabis plant which are psychoactive are listed in Schedule 1. This means that it is subject to the strictest level of control; however, under this legislation it is open to the Minister for Health to consider granting a licence to an **Irish-registered medical practitioner** for medical cannabis for a named patient. It is important to note that a licence cannot be granted in relation to the provision of cannabis for medical use to a patient in their own name.

[The Chief Medical Officer has advised that the granting of a licence](#) must be based on an appropriate application being submitted by an Irish-registered medical practitioner to the Minister for Health. The application must be endorsed by the patients' medical consultant who is responsible for the management of the patient and who is prepared to monitor the effects of the medical cannabis treatment over time.

Neither the Minister, nor the Department of Health can make the clinical decision that medical cannabis would be appropriate for the treatment of an individual's health. The safety and efficacy of cannabis in a large number of medical conditions has yet to be proven. Such products should only be considered for use, after consultation with an individual's medical advisors and where conventional/existing, evidence-based treatments or therapies have proven unsuccessful or inappropriate for the patient.

It will always be the decision of the clinician, in consultation with their patient, to prescribe or not prescribe a particular treatment, including cannabis-based treatments, for a patient under their care. The Minister for Health has no role in this clinical decision-making process.

- **Medical cannabis clinical guidelines**

Disclaimer

This Clinical Guide does not replace professional judgment on particular cases, whereby the clinician or health professional decides that individual guideline recommendations are not appropriate in the circumstances presented by an individual patient, or whereby an individual patient declines a recommendation as a course of action in their care or treatment plan. In these circumstances the decision not to follow a recommendation should be appropriately recorded in the patient's healthcare record.

Users of the information pertaining to medical cannabis in these webpages and in the Clinical Guide on medical cannabis must ensure they have the current version (hardcopy or softcopy) by checking the relevant section in the Department of Health website.

Clinical guidelines for prescribers have been drawn up by an expert group of doctors, pharmacists, patient representatives and scientific experts, to support the Medical Cannabis Access Programme, which is currently under development. [These clinical guidelines are available here.](#)

While these guidelines will primarily underpin the functioning of the Access Programme, the Department invites all clinicians with an interest in considering use of a cannabis-based treatment for their patient to review the information contained within.

As the guidelines were drawn up by an expert group from a range of healthcare and research disciplines, it is also suggested that clinicians who wish to apply to the Minister for Health for a licence to use cannabis for medical purposes for indications which are outside of the Access Programme should refer to the guidelines before submitting their application.

- **Applying to the Minister for Health for a medical cannabis licence**

Where an Irish-registered medical practitioner wishes to consider using cannabis as a treatment for their patient, a licence can be requested from the Minister for Health. In all cases, certain strict conditions must be met in order for such a request to be considered valid.

- **Who can apply for a medical cannabis licence**

It is important to note that cannabis for medical use licence applications can only be accepted by the Minister for Health from:

- an individual patient's medical consultant, where evidence of an established doctor-patient relationship exists,

or

- from the individual patient's General Practitioner (GP) where the GP's licence application is accompanied by a written endorsement for the cannabis treatment from the patient's medical consultant.

To see the requirements for the granting of a Ministerial licence and information on how to apply please see the **Ministerial Licence Application Process** section below.

- **Medical Cannabis Access Programme**

The Minister intends to introduce a Cannabis for Medical Use Access Programme. This programme is under development and it will facilitate access to cannabis products, which are not authorised as medicines, for patients suffering from a limited number of medical conditions.

- **Difference between cannabis-based medicines and cannabis-based products**

Under Irish and EU law, medicinal products (medicines) are required to be authorised before they are placed on the market. Medicinal products must demonstrate their quality, safety, and effectiveness based on clinical trial data in order to receive their authorisation. Authorisations are issued by either a national competent authority such as the HPRA or by the European Medicines Agency. Authorised medicines have a positive benefit/risk profile and are subject to on-going monitoring by regulatory authorities.

This section will explain the difference between an authorised cannabis-based medicine and a product derived from cannabis which is not authorised but which may be considered for inclusion as part of a patient's medical treatment.

- **Cannabis-based medicines**

Authorised cannabis-based medicines are manufactured from standardised extracts of the cannabis plant or created as synthetic analogues of specific cannabinoids. Authorised cannabis-based medicines have demonstrated their quality, safety, and effectiveness based on clinical trial data. They have a positive benefit/risk profile and are subject to on-going monitoring by regulatory authorities, such as the HPRA.

To date one cannabis-based medicine, Sativex, has been authorised in Ireland and is indicated for the treatment of spasticity related to Multiple Sclerosis. Prescribing of Sativex does not require a ministerial licence, under the Misuse of Drugs Acts.

Two other medicines, which have been developed based on the chemical structure of THC, have been authorised in some countries.

1. Nabilone, a synthetic analogue of THC, is authorised for controlling nausea and vomiting associated with chemotherapy, in patients who have failed to respond adequately to conventional antiemetic therapies. In Ireland, Nabilone is listed in Schedule 2 of the Regulations and is therefore not subject to the same prohibitions as the cannabis plant. It can be prescribed without Ministerial licence.
2. Dronabinol, a synthetic version of THC, is authorised for stimulating appetite in patients with AIDS-related wasting and for nausea and vomiting associated with chemotherapy. Dronabinol is listed in Schedule 1 of the Regulations and is therefore subject to the strictest level of controls and requires a Ministerial licence to facilitate it being prescribed.

Medicines, authorised in Ireland or elsewhere, including authorised cannabis-based medicines, should be used in the first instance. However, if an authorised medicine is not available or is not suitable for the patient, cannabis-based products that do not have a marketing authorisation may be considered as a treatment option, via the Ministerial licence application process, or eventually through the Medical Cannabis Access Programme, once it is established.

- **Cannabis-based products**

Cannabis-based products that do not have a marketing authorisation are not medicines as defined under national and European legislation. As such, they are not subject to the same rigorous safety, quality and efficacy standards that are in place for medicines, nor are the producers subject to the same responsibilities as the marketing authorisation holders for authorised medicines.

Whilst efficacy and safety data are not available for these products, it is important to be assured, as far as possible, of the quality of the products. These products will be required to be made to specified laboratory and manufacturing standards and are often supplied in the form of processed oils or sprays with identified levels of the cannabinoids required.

- **Availability**

Medical cannabis products that meet accepted quality standards have not, as yet, been made available by producers directly to the Irish marketplace. This is a critical aspect of facilitating access to medical cannabis for Irish-based patients. Department of Health officials are working intensively to ensure a supply of appropriate cannabis-based medical products to meet the needs of Irish patients

Glossary of terms

- **Cannabinoid** - any of a group of closely related compounds which include cannabitol and the active constituents of cannabis.
- **Tetrahydrocannabinol - also known as THC** - A psychoactive cannabinoid which is strictly controlled under the Misuse of Drugs Act.
- **Cannabidiol – also known as CBD** - A non-psychoactive cannabinoid which is not subject to control under the Misuse of Drugs Act and which is sometimes sold as a food supplement.
- **Health Products Regulatory Authority (HPRA)** - the Competent Authority for the implementation of EU and national legislation relating to medicines in Ireland. The HPRA's role includes monitoring and inspecting health products on the market to ensure their safety, efficacy and legality.
- **Psychoactive Substance** - a substance having a profound or significant effect on mental processes.
- **Misuse of Drugs Acts and Regulations** - The Misuse of Drugs Acts and the Regulations made thereunder are the main laws regulating controlled drugs in Ireland. They include controls relating to cultivation, licensing, possession, administration, supply, record-keeping, prescription-writing, destruction, storage and safe custody, import and export. They also establish the offences and penalties under the Act.

Ministerial Licence Application Process

This section contains more detailed information for clinicians who require information about the Ministerial licence application process for cannabis-based treatments.

- Under the Misuse of Drugs Act, it is open to the Minister for Health to consider granting a licence to an Irish-registered medical practitioner for access to cannabis for medical use for a named patient(s) under his or her care.
- The Chief Medical Officer has advised that the granting of a Ministerial licence for medical cannabis must be based on an appropriate application being submitted to the Department of Health that is endorsed by a medical consultant who is responsible for the management of the patient and who is prepared to monitor the effects of the treatment over time.
- A valid licence application under the Misuse of Drugs Acts must include
- An outline of the treatment the patient has received to date and justification from the doctor as to why it is appropriate, in their patient's specific circumstances, to prescribe cannabis.
- Details of the cannabis-based product which it is proposed to prescribe and administer to the patient.
- The source of the cannabis-based product.
- The arrangements for the ongoing monitoring and care of the patient once the cannabis-based treatment has commenced.

It is important to note that it will always be the decision of the clinician, in consultation with their patient, to prescribe or not prescribe a particular treatment, including cannabis treatment, for a patient under their care. The Minister for Health has no role in this clinical decision-making process.

Note - The requirements for an application to use cannabis-based treatments are subject to change as the policy on cannabis for medical purposes continues to develop.

Medical practitioners who wish to submit an application or who require further information should contact controlled_drugs@health.gov.ie

Licence applications received by the Minister for Health are assessed by Department officials for compliance with the applicable provisions of the Misuse of Drugs Acts and to ensure they are in line with the advice provided to the Minister by the Chief Medical Officer on the matter. Licence applications are not clinically reviewed. It is the responsibility of the applicant to ensure the clinical appropriateness of the proposed medical cannabis treatment for their patient.

"Neither the Minister, nor the Department of Health can make the clinical decision that medical cannabis would be appropriate for the treatment of an individual's health. The safety and efficacy of cannabis in a large number of medical conditions has yet to be proven. Such products should only be considered for use, after consultation with an individual's medical advisors and where conventional/existing, evidence-based treatments or therapies have proven unsuccessful or inappropriate for the patient."

Application Process for a Ministerial Licence

[In order to ensure a Ministerial licence application submitted by a medical practitioner is valid, a template document is available here](#), which may be used as a guide in applying for a Ministerial licence.

It is important to note that the Department of Health may request additional contact or particulars from an applicant before considering an individual application to be full and valid.

All applications are treated individually and so processing time for each application may differ, however the Department considers all valid applications as priority correspondence and will endeavour to maintain as efficient a processing system as possible.

Any personal data received as part of the application will be subject to the provisions of the General Data Protection Regulation (GDPR) and the Data Protection Acts. To process the application fully it may be necessary to share personal data with the Health Service Executive. In these circumstances the data will be shared for that one purpose only.

[For further information see the Department's Privacy Statement.](#)

Medical Cannabis Access Programme

In November 2016, the Minister for Health announced a review of policy on cannabis for medical purposes and requested the HPRA's views on recent developments in the use of cannabis for medical purposes including products available, research, indications and evidence of effectiveness, an overview of the different regulatory regimes in place in countries which allow cannabis to be used for medical purposes and legislative changes that would be required to allow use of cannabis for medical purposes in Ireland.

The HPRA established a Working Group of relevant experts to assist with its review. The experts included consultant neurologists, a consultant in palliative medicine, a consultant psychiatrist specialising in addiction, a consultant anaesthetist/pain specialist, and a palliative care pharmacist as well as patient representatives.

[The HPRA's subsequent report 'Cannabis for Medicinal Use – A Scientific Review', published in February 2017](#), recommended that if access to cannabis is to be permitted for medical purposes, that its use should only be initiated as part of a structured process of formal on-going clinical evaluation in a limited number of clearly defined medical conditions which have failed to respond to all other previous treatments, and where there is at least modest evidence that cannabis may be effective.

The report noted that all such patients should be under the direct supervision of an appropriately trained and experienced medical consultant. The specified medical conditions (medical indications) are:

- Spasticity associated with multiple sclerosis resistant to all standard therapies and interventions whilst under expert medical supervision;
- Intractable nausea and vomiting associated with chemotherapy, despite the use of standard anti-emetic regimes whilst under expert medical supervision;
- Severe, refractory (treatment-resistant) epilepsy that has failed to respond to standard anticonvulsant medications whilst under expert medical supervision.

The HPRA report further recommended the introduction of a monitored cannabis treatment programme and advised that such a programme is necessary, both to maximise the safe and effective use of cannabis as a medical therapy for an individual patient, and to minimise the potential negative impact of wider access on society. It is planned that the programme should

run for a period of five years, with a centralised data collection point and regular reports to the Department of Health. This information will provide data on the medical use of cannabis and the supply needs in Ireland.

On foot of the conclusions from the HPRA's report, the Minister established an Expert Reference Group to advise on the development of a Medical Cannabis Access Programme. The Expert Reference Group is chaired by Dr Mairín Ryan, Director of Health Technology Assessment at the Health Information and Quality Authority (HIQA). The group comprises representation from the areas of Oncology, Palliative care, Anaesthesiology, General Practice, Adult Neurology, Paediatric Neurology, Multiple Sclerosis, Psychiatry, Pharmacy, Patients, Ethics, Health Technology Assessments and the Health Products Regulatory Authority.

The Expert Group was asked to advise on the development of operational, clinical and practice guidelines for healthcare professionals treating patients through an Access Programme. An important aspect of the work of the Group was to engage with representative bodies, clinicians, patients, and pharmacists, all of whom are integral to the production of clinical and operational guides for an Access Programme. [The Group also conducted a targeted consultation on the draft form of the clinical guide, which has been finalised and is available here.](#)

Expert stakeholder engagement is being undertaken to set the quality standards to be applied to medical cannabis products that will be permitted for use under the Access Programme. This will help to ensure that many of the quality controls expected for other medicines can be applied to medical cannabis.

The Access Programme is not yet operational, as further work is required in relation to certain elements, in particular the availability of appropriate quality-approved medical cannabis products for patients. This is a critical aspect in establishing the access programme. The Department is working intensively on finding solutions to the supply of appropriate products for Irish patients.

In the meantime, prescribing of cannabis for medical treatment by medical consultants, for their individual patients is being facilitated via the Ministerial licence application route.