FREQUENTLY ASKED QUESTIONS

Q 1- What does medical use of Cannabis mean?

This describes a situation where a medical consultant prescribes the use of an acceptable cannabis-based product for treatment of a specified medical condition in a patient under his, or her care. Dried cannabis plant material, for example, dried flowers, or products that have been manufactured from components, known as cannabinoids, extracted from the cannabis plant can be used as medical treatments. Oils may also be manufactured using extracts from the cannabis plant.

Q 2- What is the Medical Cannabis Access Programme (MCAP)?

A - It is a 5-year pilot programme. The purpose of the programme is to facilitate access to acceptable cannabis-based products for medical use that are of a standardised quality and which meet the requirements outlined in the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019. The Medical Cannabis Access Programme is to provide access for patients with the following medical conditions which have failed to respond to standard treatments:

- spasticity associated with multiple sclerosis;
- intractable nausea and vomiting associated with chemotherapy;
- severe, refractory (treatment-resistant) epilepsy.

It is important to note that a listed cannabis-based product is not an authorised medicine in that it has not undergone the rigorous testing, both in laboratory and clinical trials, and authorisation process required before such medicines can be placed on the open market.

The prescribing and use of a cannabis product for the purposes of the Medical Cannabis Access Programme, is a matter for the patient and their medical consultant.

Where a cannabis product, legally permitted for medical use in connection with the Access Programme is prescribed and used, this does not signify any endorsement whatsoever by the Minister for Health as to the safety, quality or efficacy of the cannabis product for the indication prescribed.

Important: The MCAP Register is not currently operational. Healthcare Professionals and Patients are advised to consult the Department of Health website for updates.

Q 3- What medical cannabis products are acceptable under the MCAP?

A – The medical cannabis products which meet the requirements in the legislation will be listed in Schedule 1 to the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019.

The signing of this legislation by the Minister for Health allows for the commencement of the operation of the Access Programme, the first stage of which will be for potential suppliers to apply to have their medical cannabis products assessed for suitability for medical use. Please see question 10 and 11 for details on how operators can apply to have their products considered for suitability for use under the MCAP

Q 4- Why has the Minister for Health decided to introduce the MCAP?

A - The MCAP was initiated in March 2017 on foot of the conclusions from the Health Products Regulatory Authority's (HPRA) report 'Cannabis for Medical Use – A Scientific Review', which was prepared at the request of the Minister in 2016. The review concluded that, in certain cases where all other routes have been exhausted, medical cannabis is an option to treat patients who have been diagnosed with any of the three specified medical conditions.

Q5 - Who can prescribe medical cannabis under the Access Programme?

A – A registered medical consultant with specialist training in a specified medical condition, as described in the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019.

Q 6 - I am a patient and want to get more information on accessing medical cannabis, how do I go about this?

A – Cannabis for medical use should only be prescribed once other suitable and appropriate treatments have failed and based on a prescription from your consultant.
You may find it helpful to familiarise yourself with the Clinical Guidelines and further information contained on the Department of Health's website at the following link https://health.gov.ie/cannabis-for-medical-use/medical-cannabis-access-programme/
You may also discuss this with your general practitioner and your medical consultant. (See also Q 8)

Q 7- Under the new legislation for the MCAP, am I eligible to access medical cannabis?

A – The Medical Cannabis Access Programme aims to provide access for patients with the following medical conditions which have failed to respond to standard treatments and who have been prescribed cannabis treatment by their medical consultant:

- spasticity associated with multiple sclerosis;
- intractable nausea and vomiting associated with chemotherapy;
- severe, refractory (treatment-resistant) epilepsy.

Q 8 - I am a pharmacist, my patient has a prescription for a medical cannabis product under the Medical Cannabis Access Programme. What do I do next?

A - You should familiarise yourself with the new legislation which sets out the obligations for pharmacists under the operation of the MCAP. You should also familiarise yourself with the Clinical Guidelines as prepared by the Expert Reference Group. These are available on the Department of Health Website here https://health.gov.ie/wp-content/uploads/2019/04/Clinical-guidance-on-cannabis-for-medical-use-updated-26042019-final.pdf

Q 9- I am a medical consultant and I think one of my patients will be eligible to enrol in the MCAP. What do I do next?

A – A Consultant working in a medical specialty directly related to a specified medical condition, wishing to prescribe cannabis for medical use for a patient under his or her care must register with the HSE in order to access the HSE portal and they must register the patient through this portal. If registration is approved, then the Consultant can issue a prescription. Contact details for the HSE will be added shortly. (See also Q 14).
You should familiarise yourself with the new legislation which sets out the obligations for prescribers under the operation of the MCAP.
You should also familiarise yourself with the Clinical Guidelines as prepared by the Expert Reference Group. These are available on the Department of Health Website here https://health.gov.ie/wp-content/uploads/2019/04/Clinical-guidance-on-cannabis-for-medical-use-updated-26042019-final.pdf

Q 10 - I am a commercial operator and want to have a cannabis product included in the MCAP. What do I do next?
A prospective supplier will be able to apply to the HPRA, on behalf of the Minister, to have a cannabis product considered for inclusion in the schedule to the Regulations and, thereby, the product will become eligible to be prescribed under the MCAP.

Cannabis is not an authorised medicine in that it has not undergone the rigorous testing, both in laboratory and clinical trials, and authorisation process required before such medicines can be placed on the open market.

It is important to note that where a cannabis product, legally permitted for medical use in connection with the Access Programme is prescribed and used, this does not signify any endorsement whatsoever by the Minister for Health, the Health Products Regulatory Authority or the HSE as to the safety, quality or efficacy of the cannabis product for the indication prescribed.

Q11 - I am a commercial operator and want to import and supply medical cannabis products into Ireland. What will I do next?

A – Once a product has been included in the MCAP legislation, it will also be included under Schedule 2 to the Misuse of Drugs Regulations 2017. As a supplier or importer, you will be required to apply for controlled drug licences, processed by the HPRA, on behalf of the Minister. As with all Schedule 2 controlled substances, a controlled drug annual licence will be required to possess and supply the medical cannabis products included in the MCAP. Once in receipt of an annual licence, a controlled drug import license will be required to accompany each import consignment. Further details can be found on www.hpra.ie

Q 12 As a commercial operator whose cannabis products have been added to S1 of the relevant legislation, I would like to engage with the relevant Agency to obtain more information on pricing and supply
A –Contact details for queries relating to pricing and supply of Schedule 1 Cannabis-based products is:
Health Service Executive
Corporate Pharmaceutical Unit,
HSE, Primary Care Reimbursement Service,
Exit 5, M50,
Finglas,
Dublin 11.
D11XKF3

Phone No: 01 8915725
Fax No: 01 8915757
Email Address: CPU@hse.ie

Q 13- Will the scope of the MCAP be widened in the future to include other medical conditions?

A - The pilot programme will be reviewed after 5 years or as scientific evidence comes to light to support the use of cannabis for the effective and safe treatment of other medical conditions.

Q 14- I am eligible to be enrolled on the MCAP but I am concerned about the cost of the treatment?

A - Registration on the MCAP does not automatically mean approval for reimbursement. Reimbursement of approved cannabis products, supplied through community pharmacies for patients with a qualifying condition, will be on a named patient basis and according to the patient's eligibility under the community drug schemes (Medical Card, Long Term Illness and Drugs Payment Schemes) overseen by the HSE, with the following conditions:

treatment is consultant-initiated;
online reimbursement approval is required for each patient;
all standard approved treatments have been exhausted for that patient;
new patients are initiated on Irish pharmacy-supplied medical cannabis products.

Contact details for the HSE will be added shortly.
Q 15- My doctor has advised that I should not take or should stop taking medical cannabis, but I am unhappy with this decision, what do I do next?

A – Your doctor will provide you with an explanation for their decision. If you are not satisfied it is possible to seek a second opinion from another medical practitioner. 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 medical condition.

Q 16- Can I take other medication while taking medical cannabis?

A - There is a possibility of a clinically significant interaction between other prescription or over the counter medicines and health products you may be taking and cannabis-based products. Please discuss this with your medical practitioner or pharmacist. You should also read the information leaflet for the cannabis product.

Q 17- Are there any side effects to taking medical cannabis?

A - Cannabis based products can cause side effects. Some very common, some common and some uncommon. Please read the information leaflet for the product you are taking, which will contain further details.
It is important to understand that cannabis products are not being authorised as medicinal products as there is insufficient data and they have not undergone the process of authorisation required to determine the safety, quality and efficacy to the same standards as medicines
As there is limited data on benefits and potential side effects, you should immediately inform your practitioner or pharmacist if you suffer any side effect from taking the product.

Q 18- I am currently obtaining medical cannabis via a Ministerial License. Will the new legislation affect me?

A - While both the Access Programme and the Ministerial licence route will run in parallel initially, it is possible that many of the patients currently accessing cannabis treatment via the Ministerial licence route might, where that is possible, be enrolled onto the Access Programme by their medical consultant. This may involve their treating consultant switching their current prescribed cannabis product to a product that can be prescribed under the MCAP. It may not be possible for all the current Ministerial licence holders to transfer immediately; however, this will be based on a clinical decision between the patient and their prescriber.

Having consulted the above Q&A, the secondary legislation underpinning the Programme - the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019, and the Clinical Guidance document, if you do not find the information you require please submit your query to: controlled_drugs@health.gov.ie