

Medical Cannabis Policy Reform for the Republic of Ireland

Policy Proposal on Clinics, Patient Access, Investment, International Patients, and Expanded Indications

Prepared for: Oireachtas Members, the Department of Health, HSE, HPRA, and Relevant Stakeholders

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Purpose: To advocate for comprehensive reform of the Medical Cannabis Access Programme (MCAP) and associated legislative frameworks in the Republic of Ireland.

Executive Summary

Medical cannabis is legal in Ireland only under tightly controlled circumstances through the Medical Cannabis Access Programme (MCAP) and ministerial licensing under the Misuse of Drugs Acts 1977- 2016 and associated regulations. The MCAP is a five-year pilot programme designed to provide access to cannabis-based products for patients with specified conditions that have failed to respond to standard treatments.

Currently, only three conditions qualify under MCAP: spasticity associated with multiple sclerosis, severe refractory epilepsy, and intractable chemotherapy-induced nausea and vomiting, all under specialist consultant supervision.

While recent regulatory amendments and reimbursement arrangements have modestly improved access, the system remains overly restrictive, administratively burdensome, and commercially unattractive. Patients face limited clinical pathways, a narrow eligibility list, and an absence of clear provisions for international patients travelling with prescribed medical cannabis.

This policy document proposes an integrated reform package built on five pillars:

1. **Expansion and formal licensing of medical cannabis clinics** across Ireland.
2. **Easier, more equitable patient access** through broader indication criteria and streamlined prescribing pathways.

3. **Reduction of regulatory red tape** to enable sustainable investment and growth in the Irish medical cannabis industry.
4. **A clear framework for international patients** to enter Ireland with their legally prescribed medical cannabis, subject to safeguards.
5. **Expansion of recognised medical indications** for which medical cannabis can be prescribed within a supervised, evidence-based framework.

These reforms align with international best practice, respect Ireland's obligations under EU and international law, and present an opportunity to enhance patient care while positioning Ireland as a responsible, innovation-friendly medical cannabis hub.

Background: Current Framework in Ireland

Legal and Regulatory Context

Cannabis containing tetrahydrocannabinol (THC) is strictly controlled under the Misuse of Drugs Acts and the Misuse of Drugs Regulations 2017, where it is listed in Schedule 1 as a substance subject to the highest level of control. The MCAP was first enabled in 2019 to facilitate compassionate access to cannabis-based products where conventional treatment has failed, following the HPRA's scientific review "Cannabis for Medical Use".

The MCAP operates through the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019 and subsequent amendments, most recently S.I. No. 229 of 2025, which refine prescription and supply controls for cannabis for medical use. In parallel, clinicians may seek ministerial licences on a named-patient basis for products and indications outside the MCAP, under strict conditions and with detailed clinical justification.

Access Pathways and Current Limitations

There are two primary routes for accessing medical cannabis in Ireland:

- **MCAP route:** For patients with one of three specified conditions who are under the care of a specialist consultant and registered on the Cannabis for Medical Use Register.
- **Ministerial licence route:** For individual named patients, typically for conditions such as chronic pain, certain psychiatric and neurological conditions, oncology, and palliative care, subject to detailed clinical application and approval by the Minister.

Under the HSE Medical Cannabis Products Reimbursement Scheme, eligible patients with one of the three MCAP conditions can apply for funding of approved cannabis-based products, but the process requires consultant involvement and significant documentation. Access is further constrained by the limited list of approved products and the small number of Irish-based clinics with expertise in cannabinoid medicine.

Internationally, several EU states and other jurisdictions have moved towards more structured clinic-based models, wider indication lists, and clearer provisions for travelling patients with prescribed medical cannabis. Ireland remains comparatively restrictive.

Policy Pillar 1: Licensing and Expansion of Medical Cannabis Clinics

Problem Statement

Although at least one private medical cannabis clinic now operates in Ireland and facilitates access via MCAP and ministerial licence routes, there is no dedicated national licensing framework for medical cannabis clinics as such. Access remains highly dependent on a small number of consultants and clinics, resulting in long waiting times, regional disparities, and a lack of integrated care pathways between primary and secondary care.

Most patients must still navigate hospital-based specialist services to obtain prescriptions, and many GPs are hesitant to engage with medical cannabis prescribing due to regulatory uncertainty, training gaps, and perceived professional risk. This restricts the development of community-based care and creates barriers for patients in rural or underserved areas.

Policy Proposals

1. **Create a statutory medical cannabis clinic licence category** under HPRA and Department of Health oversight, defining standards for staffing, governance, record-keeping, pharmacovigilance, and patient safety.
2. **Permit both public and private clinics** to apply for licences, including community-based centres and integrated services within existing primary care networks.
3. **Require mandatory clinical training** in cannabinoid medicine for prescribing clinicians working in licensed clinics, with accreditation recognised by the Medical Council.

4. **Enable telemedicine consultations** within the regulatory framework, particularly for follow-up and stable patients, to improve access across the State, while maintaining safeguards for initial assessments.
5. **Mandate data contribution** from licensed clinics to a national medical cannabis registry, supporting real-world evidence collection and policy evaluation.

Rationale

A formal clinic licensing model will normalise and professionalise medical cannabis prescribing, ensure consistent standards of care, and expand capacity beyond a small number of consultants. It will also provide regulatory clarity for investors and healthcare providers seeking to establish compliant services in Ireland.

Policy Pillar 2: Easier, Equitable Patient Access

Problem Statement

The MCAP currently restricts access to three conditions: spasticity associated with multiple sclerosis, severe refractory epilepsy, and intractable chemotherapy-related nausea and vomiting. Patients with chronic pain, PTSD, anxiety disorders, insomnia, inflammatory bowel disease, fibromyalgia, and other conditions for which emerging evidence supports cannabinoid therapy generally must rely on the ministerial licence route, which is administratively heavy and uncertain.

Additionally, only hospital consultants can currently prescribe under MCAP, creating bottlenecks and reducing accessibility for patients whose care is largely delivered in primary care. Funding arrangements, while improved by HSE direct payments for some ministerial-licence patients, remain complex and inconsistent.

Policy Proposals

1. **Expand the MCAP indication list** to include, at minimum:
 - Chronic neuropathic pain and other chronic pain syndromes where standard therapies have failed.
 - PTSD and certain treatment-resistant anxiety and depressive disorders.
 - Movement disorders (Parkinson's disease, multiple sclerosis beyond spasticity), chronic fatigue and some neurodegenerative conditions.

- Inflammatory bowel disease (Crohn's disease and ulcerative colitis).
 - Oncology-related symptoms and palliative care indications.
2. **Introduce tiered prescribing authority:**
 - Specialist consultants retain responsibility for complex and high-risk cases.
 - Trained General Practitioners can initiate and continue prescribing for specified indications within evidence-based protocols.
 3. **Standardise reimbursement** by integrating MCAP products and eligible ministerial-licence products into existing community drug schemes (Medical Card, Drug Payment Scheme) with clear criteria.
 4. **Simplify registration and renewal** processes for patients on stable treatment regimes, allowing annual reviews rather than frequent re-application.
 5. **Develop national clinical guidelines** for medical cannabis prescribing, including dosing, monitoring, contraindications, and interactions, to support clinicians and safeguard patients.

Rationale

Expanding indications and enabling GP participation will bring Ireland closer to international best practice while maintaining a structured, supervised clinical framework. It will reduce reliance on exceptional ministerial licences and ensure that patients with serious, treatment-resistant conditions are not excluded solely because their condition is not on a narrow list devised for an initial pilot programme.

Policy Pillar 3: Reducing Red Tape and Enabling Investment

Problem Statement

Suppliers and prospective domestic producers face a complex regulatory landscape involving HPRA product assessment, controlled drug licensing, import/export controls, and fragmented administrative processes. The limited number of approved products under MCAP and the absence of a clear pathway for domestic cultivation have constrained competition, innovation, and price reductions for patients.

Ireland's broader reputation as a pharmaceutical hub contrasts sharply with the slow and cumbersome development of its medical cannabis sector, which lags behind countries such as Germany, the Netherlands and Denmark.

Policy Proposals

1. **Implement mutual-recognition pathways** for cannabis-based medical products already authorised or registered for medical use in other EU member states or trusted jurisdictions, subject to HPRA verification of quality and safety.
2. **Create a single-window application system** combining HPRA product listing, controlled drugs licensing, and import/export authorisations into a unified, time-bound process with published service standards.
3. **Develop a domestic cultivation and processing licence regime** allowing Irish-based operators to grow, manufacture, and potentially export medical cannabis products under GMP and HPRA oversight.
4. **Offer targeted investment incentives** (e.g., R&D tax credits, IDA-supported grants, and clustering initiatives) for medical cannabis research, clinical trials, and manufacturing.
5. **Establish a Medical Cannabis Industry Advisory Group** within the Department of Health and/or HPRA, including patient representatives, clinicians, industry, and regulators, to regularly review market performance and recommend regulatory adjustments.

Rationale

A clearer, streamlined regulatory environment will attract responsible investment, broaden product availability, and foster research, while maintaining strict quality and safety standards. Leveraging Ireland's pharmaceutical expertise can generate employment, tax revenue, and export opportunities in a fast-growing global market.

Policy Pillar 4: International Patients Travelling with Medical Cannabis

Problem Statement

Official Irish guidance and independent travel information emphasise that cannabis-based products cannot be freely brought into Ireland, even when prescribed for medical use abroad. In

practice, international patients may face seizure of medication at points of entry and risk criminal liability, creating fear and uncertainty.

At the same time, Ireland already permits travellers to bring limited quantities of other controlled medicines, subject to documentation and, for some Schengen residents, Article 75 certificates. The absence of a clear, compassionate framework for medical cannabis is increasingly out of step with developments in other jurisdictions.

Policy Proposals

1. **Introduce a Visiting Patient Medical Cannabis Protocol** allowing international patients with valid prescriptions or medical certificates from recognised jurisdictions to carry a defined personal supply (e.g., up to 30 days) of prescribed cannabis-based medicine into Ireland.
2. **Establish a pre-travel notification system** whereby patients or their clinicians can register details of their prescription and travel itinerary with a designated Irish authority (e.g., HPRA or Controlled Drugs Unit) before arrival.
3. **Issue clear operational guidance** to Revenue (Customs), An Garda Síochána, and port and airport authorities on recognising compliant documentation, verifying authenticity, and managing suspected non-compliance.
4. **Align quantity and documentation requirements** with existing controlled medicine travel rules as far as possible, while specifying that unauthorised diversion or supply remains prohibited.
5. **Provide for exceptional authorisations** (similar to ministerial licences) in cases where patients require larger quantities due to extended stays, with appropriate safeguards.

Rationale

A transparent, humane framework for visiting patients will protect patient welfare, avoid unnecessary seizures of essential medicines, and support Ireland's tourism and healthcare sectors. It can be designed in a manner that is fully consistent with Ireland's international drug control obligations.

Policy Pillar 5: Expanded and Evidence-Based Medical Indications

Problem Statement

The current MCAP indication list reflects an early, highly cautious approach informed by initial HPRA advice to limit access to a small number of conditions with modest evidence of efficacy. Since then, international experience and research have expanded the evidence base for cannabis-based medicines in chronic pain, certain psychiatric conditions, spasticity, movement disorders, and palliative care.

Retaining an extremely narrow indication list risks leaving patients without access to potentially beneficial therapies and perpetuates inequity between those who can secure ministerial licences and those who cannot.

Policy Proposals

1. **Mandate a periodic scientific review** (e.g., every three years) of the evidence base for medical cannabis across conditions, conducted by HPRA with external clinical and patient input.
2. **Adopt a tiered indication framework** distinguishing:
 - Conditions with strong evidence and established dosing protocols.
 - Conditions with emerging evidence warranting supervised, monitored use within registries or controlled access schemes.
 - Conditions where evidence is insufficient, but compassionate use may be considered under strict criteria.
3. **Integrate ministerial-licence indications** with MCAP where sufficient evidence and experience have accumulated, reducing the reliance on exceptional licences.
4. **Ensure that expanded indications are coupled with data collection**, including patient-reported outcomes, to refine clinical guidance over time.
5. **Publish clear patient-facing information** on conditions for which medical cannabis may be considered, eligibility criteria, and pathways to access.

Rationale

An adaptive, evidence-based indication framework will allow Ireland to respond to evolving scientific knowledge while maintaining appropriate caution. It will also support clinicians in making informed prescribing decisions and reduce uncertainty for patients.

Implementation Roadmap

Reform Area	Lead Body	Key Supporting Bodies	Suggested Timeline
Clinic licensing framework	Department of Health / HPRA	Medical Council, HSE	12–18 months
Expansion of MCAP indications	HPRA / Department of Health	HSE, clinical colleges	6–12 months
GP prescribing and guidelines	Department of Health / Medical Council	ICGP, HSE	12–18 months
Streamlined licensing and mutual recognition	HPRA	Revenue, Dept. of Enterprise	12–18 months
Domestic cultivation framework	HPRA / Dept. of Agriculture	Dept. of Enterprise, IDA	18–24 months
International patient protocol	Department of Health	HPRA, Revenue, Garda Síochána	6–12 months
National registry and data systems	HSE	HPRA, licensed clinics	12–18 months

Timelines assume political commitment and adequate resourcing. Many reforms can be progressed in parallel through a cross-departmental implementation group.

This policy document is intended as a template and advocacy tool. It should be read alongside up-to-date legislation, HPRA guidance, and Department of Health policy publications to ensure alignment with current law and practice.