ARTHUR COX

Group Briefing
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Cannabis Regulation in Ireland

Ireland Client Service Law Firm of the Year 2018
Chambers Europe Awards

Ireland Law Firm of the Year 2018
International Financial Law Review (IFLR) Europe Awards

Ireland Law Firm of the Year 2018
Who's Who Legal

Ireland Law Firm of the Year 2017
Chambers Europe Awards

Best Firm in Ireland 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm for Women in Business Law 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm Mentoring Programme 2018, 2017 & 2016
Europe Women in Business Law Awards

Best National Firm for Minority Women Lawyers 2018
Europe Women in Business Law Awards

Access to medicinal cannabis is a growing healthcare issue in Ireland. Medicinal cannabis is legally available in many countries. Canada opted for a radical approach in October when it gave the green light to both medicinal and recreational cannabis. The UK and Northern Ireland, as of 1 November this year, approved the prescription of cannabis-based products for medicinal use without obtaining a licence from the Government.

IRISH REGULATORY FRAMEWORK

As the law currently stands, cannabis, cannabinol and cannabinol derivatives are listed as Schedule 1 controlled substances under the Misuse of Drugs Act 1977, as amended, (the "**Acts**"), meaning cannabis products are subject to the strictest level of control. Unless used for research, forensic analysis or as an essential material in an industrial manufacturing process, the manufacture, supply, distribution and/or possession of cannabis is illegal.

The legislation prohibits doctors and pharmacists from prescribing, compounding and/or supplying cannabis. The Minister for Health may issue a licence to a doctor or pharmacist enabling them to conduct these activities, similar to a named-patient procedure for unauthorised medicines. Critically, it is up to the prescriber and their patient to source the product, which sometimes means travelling to the Netherlands or Canada. Despite being available for some time, the first ever licence in Ireland was granted at the end of 2016 for a three-year-old boy suffering from a severe form of epilepsy. Since then, there are reports that the Minister for Health has issued eight more licences. But the availability of products in Ireland remains a major patient roadblock.

When discussing controlled substances, it is important to distinguish between cannabis products that are psychotogenic and those that are not, the latter not being subject to "controlled substances" restrictions. The main "*active ingredients*" of cannabis are cannabinoids. Of those, CBD (cannabidiol) and THC (tetrahydrocannabinol) seem to offer the most value with respect to

clinical use. However, THC is the main psychotogenic component of cannabis and because of its hallucinogenic effects, it is a controlled substance under the Acts.

CBD, on the other hand is not considered a controlled substance due to its lack of psychotogenic effects. Nevertheless, availability of CBD for medicinal use is restricted due to existing legislation for drugs as was the case for Sativex, which was the first authorised cannabis-based drug available in Ireland. This meant that the product had proved a clear medical benefit based on evidence from scientific studies demonstrating the quality, safety and efficacy of the product.

Otherwise, CBD can only be made available as a food supplement, which means that no medicinal claims can be made with respect to the product. This is an important distinction because if applied incorrectly, products will inevitably fall foul of one or the other regulatory regime. It is interesting to note that the availability of CBD products as food supplements is growing both online and over-the-counter, examples include CBD oil, hemp oil or hemp seed oil.

CHANGING TIMES?

There has been a shift in Ireland following the Government commissioned report released by the Health Products Regulatory Authority (**HPRA**). This report was published in response to a number of media campaigns following growing public pressure. In its report, the HPRA stated that medicinal cannabis should only be available once the product has gone through the normal regulatory approval pathway for drug products i.e. with appropriate clinical data supporting the quality, safety and efficacy of the product.

However, perhaps reflecting the public mood, they were willing to entertain the idea of a controlled access programme for products that are not capable of being authorised as a medicinal product. A controlled access programme would inevitably remove the obligation on doctors or pharmacists to apply for a ministerial license in order to provide patients with access to cannabis products. It is difficult to determine with any degree of certainty how the controlled access programme will operate but it is likely to be subject to the following:

- Access should be time limited.
- Access should be limited to patients with:
  - spasticity associated with MS resistant to all standard therapies;
  - intractable nausea and vomiting associated with chemotherapy which is resistant to standard anti-emetic regimens; and
  - severe refractory epilepsy that is resistant to standard anticonvulsant treatments.
- All standard methods of treatment must be exhausted.
- The programme should not be used for authorised cannabis medicines.
- Patients should be under the direct supervision of an appropriately trained and experienced medical consultant.

A government appointed Expert Reference Group is advising on the establishment of the access programme. One of their tasks was to publish clinical guidance to provide practical information to healthcare professionals who are prescribing, dispensing and monitoring cannabis-based products. In addition to prescribing and consultation guidance, the document lists the products available under the access programme for the conditions listed above. For this initiative to be worthwhile, the products must be reimbursed and available on the Long-Term Illness (LTI) Scheme when approved.

WHAT'S NEXT?

We can expect to see the roll-out of a medicinal cannabis access programme in the short to medium term in Ireland. Whilst this scheme has been acknowledged by the Government as being under development, no legislation has yet been tabled. It is impossible to say when the scheme will be established and operational. In the interim, applications for ministerial licences to grant access to cannabis for medicinal purposes may still be made. We will continue to monitor and report on any updates.

SUMMARY TABLE OF CANNABIS REGULATION IN IRELAND

	CBD	THC
Medicine	✓ ∗ Sativex contains both CBD and THC. No authorised CBD-only medicine available as of yet but Epidiolex is currently going through EU drug approval process.	✓ ∗Sativex contains both CBD and THC. Dronabinol and nabilone are derivatives of THC but neither are authorised as a medicine in Ireland.
Food Supplement	✓ ∗No medicinal claims and must have less than 0.2% THC according to FSAI website.	✗
Unauthorised medicine	✗	✓ ∗ but only via Ministerial License or Controlled Access Scheme (when functional)

KEY CONTACTS

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