



LEGALINK

INTERNATIONAL BUT PERSONAL

CANNABIS REGULATION
AND CANNABIS
DERIVED PRODUCTS



INTRODUCTION

As more jurisdictions around the world move to legalize various forms of cannabis, including hemp and CBD products, recreational marijuana, and medical marijuana, the global cannabis industry continues to blaze forward. But changing and even inconsistent laws and an evolving regulatory environment have created legal uncertainties and tensions in the development of the industry and marketplace. This booklet aims to provide practitioners a summary reference for cannabis laws and regulations in various jurisdictions across the globe. Practitioners should note that because cannabis laws are quickly evolving, through the legislative process, ballot initiatives and regulatory rule implementations and changes, each jurisdiction's most recent cannabis laws and regulations should be reviewed and assessed.

A QUICK PRIMER ON CANNABIS BASICS

Cannabis vs. Marijuana vs. Hemp

Cannabis refers to a genus of plants that has three species - indica, sativa, and ruderalis. Marijuana and hemp are both cannabis. Despite popular misconception, marijuana and hemp are not different species of cannabis.

Marijuana, in the common parlance, is cannabis that, when consumed, results in a "high." The "high" in marijuana is produced as a result of high tetrahydrocannabinol or THC content. Hemp, again in common usage, does not cause intoxication because it has low levels of THC.

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Some jurisdictions around the world still do not distinguish between marijuana and hemp. For example, for decades, the federal government in the U.S. did not distinguish between hemp and marijuana or the level of THC content in either – both were illegal cannabis and a controlled “Schedule I” drug.

As cannabis laws and policy have changed over the years, now, in the U.S. and, as applicable, in other jurisdictions, the legal difference between marijuana and hemp is often based upon THC content level. In the U.S., again by way of further example, the Agriculture Improvement Act of 2018 defines legal hemp as “Plant Cannabis sativa L. and any part of that plant, including cannabinoids with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” Thus, under federal law in the U.S., cannabis that has no more than 0.3% THC is legal hemp, but cannabis that contains more than 0.3% remains illegal marijuana. Each jurisdiction’s definitions for each should, of course, be consulted to determine whether hemp and marijuana are distinguished from one another and where the lines of cannabis legality or illegality are drawn.

THC vs. CBD

THC and CBD are both cannabinoids found in cannabis. A cannabinoid is a naturally occurring compound that reacts with cannabinoid receptors found in our nervous system that are part of our endocannabinoid system, involved in appetite, mood, and sensing pain.

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As noted, THC is a psychoactive cannabinoid in marijuana that produces a “high.” CBD, or cannabidiol, is a non-psychoactive cannabinoid that may have some health benefits. But more studies are needed. CBD can be derived or extracted from hemp and marijuana. Many CBD products are derived from hemp, containing low levels of THC and higher levels of CBD. Whether CBD or CBD products are legal in any particular jurisdiction will be driven by legal definitions and parameters established by applicable regulatory authorities.

UNITED KINGDOM MISHCON DE REYA

This summary represents the cannabis and cannabis derived products regulatory framework in the UK as of 3rd July 2020.

1. What regulatory frameworks are relevant to medical and recreational cannabis and the cultivation, manufacture, distribution etc of cannabis and cannabinoids in the UK?

Medicinal:

Where CBD is used for medicinal purposes, such product will constitute a "medicine" and will therefore need to be subject to an MHRA licence, unless subject to a possible exemption. MHRA Guidance Note 8 includes a useful appendix on CBD-containing products. Marketers without a licence must not make medicinal claims in advertisements for products containing CBD.

The Misuse of Drugs (Amendments) (Cannabis and Licence Fee) (England, Wales and Scotland) Regulations 2018 became law on 1st November 2018. Under the regime which was implemented as an amendment to the Misuse of Drugs Act, where a CBD medicinal product is not subject to a marketing authorisation granted by the MHRA, it can only be prescribed by a specialist doctor on the General Medical Council's specialist register, and general practitioners are unable to prescribe it. Additionally, medical cannabis can only be prescribed when there is an "exceptional clinical need". How each specialist will interpret this remains to be seen, but the intention is that medical cannabis should not be prescribed unless established alternative treatments have proved to be ineffective in a particular case. If the doctors do not meet these criteria and prescribe medical cannabis which contains any THC, they risk committing a criminal offence under the Misuse of Drugs Act.

While specialists have a wide discretion on what products they prescribe, clinicians will not be permitted to prescribe the smoking of the cannabis product. The new law has met resistance from doctors, particularly those specialising in pain relief, and the debate over the overall efficacy and long-term safety profile of medical cannabis continues.

Non-medicinal:

In January 2019, the European Commission categorised CBD extracts as a “novel food” in the Novel Foods Catalogue, under Regulation (EU) 2015/2283. The UK’s Food Standards Agency subsequently accepted the Commission’s position. This means that businesses looking to sell CBD ingestibles in the UK must submit an application to the European Commission and the European Food Safety Authority (EFSA) by 31 March 2021 for approval to sell their CBD products in the UK.

The Advertising Standards Authority (ASA), regulating UK adverts, has stated that it understands that CBD products tend to be either medicines or food, and will regulate the CBD products accordingly.

Local trading standards authorities and local authorities also monitor the sale of CBD products both prior to and after the 31st March 2021 deadline and can remove any offending CBD products.

2. [What are the regulatory challenges in allowing the medical and recreational use of cannabis and cannabinoids in the UK?](#)

While the development in the law for medical cannabis is in some ways positive, the implementation leaves much to be desired. There is concern over the restrictiveness of the regime, as medical cannabis can only be prescribed by specialist doctors and for exceptional clinical need. While the caution of the Government is understandable, there is an argument that this does not reflect the new reality. Following the announcement by the Chief Medical Officer that there was evidence of the therapeutic benefit of medical cannabis, it is believed that sales of (at least) CBD oil have risen significantly. If people are unable to gain access to medical cannabis, the speculation is that they will look to self-medicate by obtaining products from unregulated sources, of which there are many, with unproven manufacturing standards and formulation.

If a novel food is liable to have an effect on human health, the Commission will request the EFSA to carry out a risk assessment as part of assessing the novel food application. We anticipate that this will be the case for CBD, given the reported issues surrounded the health effects of CBD. This means that a large body of information, including safety assessments, will be required in order to make a novel food application.

Each novel food application and approval subsequently granted is for a particular CBD product only, and, as such, applications cannot be reused for similar products. A novel food applicant may also request confidentiality over its application which, if granted, would mean that key aspects of its research evidence base are confidential and unavailable to others for five years. Therefore, other manufacturers cannot rely on the application even if their CBD products are bioequivalent.

There is very limited guidance available from the European Commission and the EFSA on what is required for novel food applications, which may make gaining approval very challenging.

In addition, whilst the UK has left the European Union, the UK remains in the transition phase and so the obligation to submit the novel foods application to the Commission continues until 31st December 2020. The FSA will take over novel food applications from 1st January 2021.

We anticipate that unless there is a very significant level of collaboration between producers of CBD products to meet the safety assessment requirements, many of the current CBD products on the market will cease to be available.

3. What regulatory frameworks are relevant for the cultivation, manufacture and supply of medicinal and recreational cannabis products in the UK?

Please refer to Question 1.

4. Which body is responsible for legislative controls relating to CBD?

A Home Office licence is currently required to import, export, produce, supply or possess CBD products which contain even a trace of THC. See above.

As mentioned above, where CBD is used for medicinal purposes, it will be subject to an MHRA licence unless subject to a possible exemption. Where a CBD medicinal product is not subject to an MHRA licence, it can only be prescribed by a consultant and for exceptional clinical need.

As noted above, the UK's FSA have aligned with the Commission's position: CBD is a novel food and must be regulated as such and be the subject of a novel food application.

5. Is there any possibility to commercialise CBD products without a Novel Food approval or medicinal product marketing authorisation in the UK?

CBD-infused cosmetic products are readily available for sale in the UK, particularly within the wellness and natural beauty sectors. Provided the CBD ingredient is not sourced from the flowering or fruiting tops of the cannabis plant and does not contain any THC, CBD can be used in cosmetics in the UK market.

Until 31st March 2021, businesses will be permitted to sell their existing CBD ingestibles without novel food approval, provided that they are not incorrectly labelled, are not unsafe to eat and do not contain any substances which fall under drug legislation. Local trading standards authorities and local authorities can monitor these CBD products and remove them from sale if they fail to meet these requirements. After 31st March 2021, only those CBD products which are the subject of a novel food application will be permitted to remain on sale.

There is little regulation of CBD vapes save that CBD vapes must comply with the General Product Safety Regulations 2005, which is a broad umbrella regulation that requires all products to be safe in their normal and foreseeable usage. We do not expect this lacuna in regulation to continue.

6. What are the testing specifications in the UK for determining the compliance of CBD with regulatory requirements (i.e. what are the testing specifications for determining the purity and/or level of any controlled substances in CBD?) and what documentation or evidence would need to be submitted to the regulatory authority in this regard?

Under the Misuse of Drugs Regulations 2001, if certain criteria are fulfilled, "exempt product" status allows up to 1 mg of a controlled substance within a product container without it being rendered illegal. The Home Office has clarified that it considers "container" to mean bottle or packet and not per dose. However, the Home Office position remains that, if CBD contains any THC, a Home Office licence is nonetheless required.



Given that cannabis is a controlled substance in the UK, the 1 mg threshold also applies to all cannabis products.

7. Are there any regional limits on the quantity of CBD that can be purchased or imported?

Not that we are aware of.

Contacts in the firm

Martyn Hann
Partner and Head of the Life Sciences Group
Email: Martyn.hann@mishcon.com

Oliver Felton
Legal Director - Dispute Resolution
Email: Oliver.Felton@mishcon.com

Stefania Littleboy
Managing Associate - Life Sciences
Email: Stefania.littleboy@mishcon.com

Emily Dorotheou
Associate - Commercial
Email: Emily.dorotheou@mishcon.com

Raina Singh
Indian Qualified Lawyer - Intellectual Property
Email: Raina.singh@mishcon.com



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