



Will the
cannabis
industry be
allowed to
blossom?

Attracting Investor Interest

In the following pages,
IR Global members will help
you understand how to adapt
to the emerging opportunities
the cannabis industry has to
offer. As the industry grows,
we will need to adapt to a fast-
changing legal landscape that
accompanies it. [Read more here](http://www.irglobal.com/publications)
www.irglobal.com/publications

IR Global – Going Beyond Expectations

IR Global was founded in 2010 and has since grown to become the **largest practice area exclusive network of advisors in the world**. This incredible success story has seen the network awarded Band 1 status by Chamber & Partners, featured in Legal 500 and in publications such as The Financial Times, Lawyer 360 and Practical Law, among many others.

The group's founding philosophy is based on bringing the best of the advisory community into a sharing economy; a system that is ethical, sustainable and provides significant added value to the client.

Businesses today require more than just a traditional lawyer or accountant. IR Global is at the forefront of this transition, with members providing strategic support and working closely alongside management teams to help realise their vision. We believe the archaic 'professional service firm' model is dying due to it being insular, expensive and slow. In IR Global, forward-thinking clients now have a credible alternative, which is open, cost effective and flexible.

Our Founding Philosophies

- **Multi-Disciplinary**

We work alongside legal, accountancy, financial, corporate finance, transaction support and business intelligence firms, ensuring we can offer complete solutions tailored to the client's requirements.

- **Niche Expertise**

In today's marketplace, both local knowledge and specific practice area/sector expertise is needed. We select just one firm, per jurisdiction, per practice area, ensuring the very best experts are on hand to assist.

- **Vetting Process**

Criteria is based on both the quality of the firm and the character of the individuals within it. It's key that all of our members share a common vision towards mutual success.

- **Personal Contact**

The best relationships are built on trust and we take great efforts to bring our members together via regular events and networking activities. The friendships formed are highly valuable to the members and ensure client referrals are handled with great care.

- **Co-Operative Leadership**

In contrast to authoritarian or directive leadership, our group puts teamwork and self-organisation in the centre. The group has steering committees for 12 practice area and regional working groups that focus on network development, quality controls and increasing client value.

- **Ethical Approach**

It is our responsibility to utilise our business network and influence to instigate positive social change. IR Global founded Sinchi, a non-profit that focuses on the preservation of indigenous culture and knowledge and works with different indigenous communities/tribes around the world.

- **Strategic Partners**

Strength comes via our extended network. If we feel a client's need is better handled by someone else, we are able to call on the assistance of our partners. First priority is to always ensure the client has the right representation whether that be with a member of IR Global or someone else.



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FOREWORD

Back in bloom: Why cannabis is now big business

In a sign that the cannabis industry is attracting investor interest far beyond just alternative lifestyle, health and wellness entrepreneurs, even the UK's Channel 4 broadcasting company has got in on the investment act – or rather its venture capital arm has.

Recently, C4 Ventures invested in cannabis company Cannaray, eyeing the wider European market for medicinal cannabis and CBD products. Cannaray is a European medical cannabis and retail CBD company that also received financial backing from Three Bridges Private Capital and Alpha Blue Ocean.

The head of C4 Ventures, Vinay Solanki, said the investment reflected the rapid use of medical cannabis and CBD across the UK and EU. As a first in UK media, the investment would give Cannaray's flagship wellness CBD brand access to a "high-reach upmarket TV audience" in the UK.

Solanki said: "We've been impressed with the leadership team at Cannaray and their progress in building a portfolio spanning European Medical Cannabis and the Cannaray CBD wellness brand.

"In 2021, Cannaray became the UK's first major brand to advertise CBD on TV and Cannaray CBD is now stocked on Amazon and in more than 1,500 retail outlets across the UK including Tesco, Superdrug, Asda, Waitrose and Harrods."

"Cannaray CBD is now stocked on Amazon and in more than 1,500 retail outlets across the UK including Tesco, Superdrug, Asda, Waitrose and Harrods."

Cannabis health benefits

V4's investment and media campaign reflects the huge emerging market growth of medicinal cannabis and CBD attributed to consumer awareness of the health benefits now available from cannabis. As well as health, wellness and medical applications, cannabidiol oil is also being used to treat depression and anxiety, diabetes and even cancer symptom relief.

Experts predict that the UK's medical cannabis market alone could be worth more than £450 million by 2026, which amounts to 24% of the total European market. Moreover, if the UK were to legalise cannabis – with recreational sales starting in 2024 – this would bring the market's size to more than £1 billion in the UK alone.

Across the EU, meanwhile, the cannabis market is expected to grow from €403 million in 2021 to reach €3.2 billion by 2025. Spain recently became the latest EU state to decriminalise cannabis for medical use, with other EU countries taking similar measures including France, Romania, Italy and Germany.

Legalisation roll out across EU and North America

Germany's federal government has its sights on a blanket legalisation of the domestic cannabis market by early 2024 – and many industry experts predict the country could well become the world's largest cannabis market within the next two years. Given that Germany has open borders with nine neighbouring countries, this would almost certainly pave the way for legalisation in other EU countries.

Elsewhere, the Canadian cannabis market continues to outpace much of the rest of the world. The sector more than doubled in value between 2019 and 2020, increasing to \$2.6 billion from \$1.2 billion. Canada is now the largest exporter of legal cannabis in the world, ahead of the Netherlands. As a result, CBD businesses are queuing up for trademarks and last year an estimated 7,000 applications and registrations were registered in the country.

To the south, the US has generally had to play catch up with Canadian legislation, where cannabis was legalised in 2018. Nevertheless, the cannabis industry has grown dramatically in the US. In the past year alone states as far apart New Jersey, Montana, South Dakota, New York and New Mexico have legalised cannabis for recreational use. Across the US, 37 states have now decriminalised cannabis for specific medical use, while 19 have gone further, for recreational use. Legislation by state governments was recently echoed by the federal government on April 1 this year when the House of Representatives voted to federally decriminalise marijuana.

Start ups, IPOs and M&As

The liberalisation of the cannabis industry and the relaxation of legislation across Europe and North America has resulted in phenomenal growth in cannabis sales. Globally, sales increased from \$21 billion in 2020 to \$29 billion in 2021 and are expected to reach \$35 billion this year, according to Jason Wilson, cannabis research and banking expert at ETF Managers Group. The result of this huge spike in growth has spawned a list of start ups, IPOs and M&As as businesses have taken advantage of the relaxation in national laws.

This growth is predicted to soar during the next decade, turning cannabis into a global industry worth \$176 billion by 2030, according to ResearchAndMarkets.com. This has also had a big impact on the legal sector where many law firms are now starting to build cannabis practice areas as the number of countries and US states introduce more relaxed laws. Legal and financial advisors are being contacted by cannabis businesses that need advice on intellectual property, employment



law, taxes, regulatory compliance, lending and financial transactions, M&As, among other practice areas.

Most lawyers agree that with legislation changing within countries and across borders, companies are now eyeing multiple business opportunities, many often involving international investment and M&As. As a result, such evolving laws and regulations require lawyers to act quickly for their clients. As an example of the complexities to hand, in one US state alone, California, cannabis companies have had to navigate 18 agencies for licensing cultivation or manufacturing, including state and local entities.

As a highly regulated industry across the world, the deregulation of the cannabis industry is now offering businesses and their advisors huge opportunities that were simply not available until recently. In this publication, legal advisors across multiple territories explain the recent changes to legislation on medicinal cannabis and CBD in their jurisdictions.

Editor

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QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

Despite recent regulatory advances, the cultivation and commercialization of cannabis is prohibited in Brazil. It is possible to import and manufacture "Cannabis Products", defined as industrialized products for medicinal purposes with vegetable derivatives or phytopharmaceuticals from cannabis sativa and the predominant presence of cannabidiol (CBD) and no more than 0.2% tetrahydrocannabinol (THC). Exceptionally, the product may contain more than 0.2% THC if intended for palliative care for patients with no therapeutic alternatives and in irreversible or terminal clinical situations.

Products outside these conditions can only be imported, manufactured or marketed if registered as a medicine/drug. Non-medical cannabis products, such as cosmetics, smokables, wellness products or food products, cannot be imported, manufactured or commercialized in Brazil. It is not allowed to cultivate cannabis in Brazil, but only to import the pharmaceutical ingredient in the permitted form. It is also prohibited to import or commercialize the plant or parts of the plant, even if it is dried, crushed or pulverized, and even if it is available in pharmaceutical form.

If certain rules are observed, a company may request authorization to import, distribute, and trade in Brazil, either through the Health Authorization for Cannabis Products, a faster process with a limited time frame for commercialization, or through its registration as a medicine, under the same terms applicable to medicines in general.

To this end, the Brazilian regulation created a special category for Cannabis Products, distinguishable from medicines, drugs, and other pharmaceutical inputs.

This text addresses the so-called Cannabis Products. Registration as a medicine follows specific rules and a considerably more bureaucratic process.

"The cultivation and commercialization of cannabis is prohibited in Brazil."

Cannabis Products (and Cannabis-based medicines as applicable) are regulated and supervised by the Brazilian National Agency for Health Surveillance ("ANVISA"), a federal autarchy linked to the Ministry of Health.

The granting of the Health Authorization requires compliance with specific requirements for marketing, prescribing, dispensing, monitoring and supervision for medicinal purposes for human use.

The Health Authorization will have an unextendable term of 5 years, during which time the registration of the product as a drug may be requested. After this period, unless registration of the drug has been obtained, the product can no longer be manufactured and imported for commercialization in Brazil.

Cannabis products must be for oral or nasal use, and there are specific restrictions related to the composition of the products. In addition, they can only be prescribed by physicians and only if other available therapeutic options have been exhausted.



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Ricardo advises the firm's clients in M&A transactions ("buy side" and "sell side"), as well as in the planning and execution of simple and complex corporate, participation, management, governance, and investment structures. In the area of investment funds, his practice focuses on Real Estate Investment Funds (FII) and Private Equity and Venture Capital Investment Funds (FIP), which led him to join the Regulation and Venture Capital Committees of the Brazilian Association of Private Equity and Venture Capital (ABVCAP) and Inovativa Brasil, the mentoring program for startups managed by the Federal Government and by the Brazilian Service of Support to Micro and Small Enterprises (SEBRAE). Ricardo is also one of those responsible for the firm's Technology and Innovation Committee.



Founded in 1954, Barcellos Tucunduva Advogados ("BTLAW") has more than 68 years of experience in business law and judicial and administrative litigation. BTLAW is based in São Paulo / SP and has offices in Rio de Janeiro and Brasília, and correspondents in the main cities of Brazil. The firm is recognized in business litigation for its high success rates in well-known cases, as well as in legal advice on highly complex issues. Predominantly focused on advising companies, BTLAW acts in Corporate Law, Startups, Banking, Financial and Capital Markets, Investment Funds, Fintechs and Payment Companies, Contracts, Real Estate, Infrastructure, Technology, Intellectual Property, Privacy and Data Protection, Labor and Tax. With a work philosophy based on the generation of results for the client, BTLAW excels as a result of the high quality of its team and the excellence in its legal services, providing personalized solutions for its clients.

QUESTION TWO

What are the different types of CBD products and how are they defined?

As we have seen, Brazilian regulation has created a special category for Cannabis Products, which is separate from the categories that previously existed, such as medicines, drugs, and other pharmaceutical inputs.

Thus, in light of Brazilian legislation and regulation, the following types of Cannabis products exist:

- Cannabis products, as defined above;
- Cannabis-based medicines that have been registered as medicines;
- The cannabis plant or its parts, which have cultivation, importation and commercialization prohibited in Brazil, even after stabilization and drying process, or in its shredded,

crushed or pulverized form;

- Other cannabis-based products that do not qualify as cannabis products or medicines, such as cosmetics, smoking products, wellness products or food and derivatives, all of which are prohibited for importation, manufacture and commercialization in Brazil.

There is no permission in Brazil for the recreational use of cannabis-based products, and planting, importing, manufacturing and commercialization for such purpose is not allowed, regardless of the quantity.

That said, Brazilian criminal law establishes a distinction between drug dealers and drug users, treating the latter less harshly, with penalties such as a warning; community service (for up to 5 months or up to 10 months in case of recidivism); an educational measure (for up to 5 months or up to 10 months in case of recidivism); and a fine.

TOP TIPS
On ensuring commercial success in your jurisdiction

- ✓ Seek specialized legal and regulatory advice in Brazil and study in advance the target market for the intended product;
- ✓ Incorporate a subsidiary in Brazil and/or enter into a commercial partnership with Brazilian company(ies) already compliant with the health regulations required for the importation, manufacture and/or commercialization of cannabis products or cannabis-based pharmaceutical products;
- ✓ Apply for Health Authorization for the importation, manufacturing and commercialization of cannabis products that meet the requirements set by ANVISA. With this, the product can be commercialized for up to 5 years;
- ✓ If applicable, apply for drug registration of the product during the term of the Health Authorization; and
- ✓ Apply for trademark or patent registration in Brazil, as applicable.

To distinguish between a dealer and a user, it is up to the judge to determine if the drug was intended for the offender's personal consumption, considering the nature and quantity, location, social and personal circumstances, and the offender's conduct and background. If trafficking is characterized, the offender may face a prison sentence of 5 to 15 years.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

The legislation on cannabis in Brazil is federal, with no differences between states and cities. Therefore, we do not see banking risks as a problem in Brazil – unlike the US, for example. The evolution of CBD research throughout the world has pushed Brazilian legislation to allow access to certain cannabis products, including the direct importation of industrialized cannabis-based products by the patients themselves, provided certain requirements are met. Still, the process is bureaucratic and difficult to access for a large part of the population. In our opinion, there are no perspectives for the release of recreational use in the short term. In any case, as this is a new market in Brazil, there are opportunities for investment in the medical cannabis market in Brazil.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

To date, the culture, manufacturing, transport, import/export, detention, offer, transfer, acquisition and use of cannabis or its varieties in France remains largely prohibited by the provisions of the Code of Public Health (CPH), even though rare exceptions exist.

The sale to consumers of raw flowers or leaves in any form, alone or mixed with other ingredients, as well as their possession by consumers or their consumption, is prohibited. However, products with tetrahydrocannabinol (THC) of less than 0.3% are now authorised for sale in France, which was not the case before.

CBD is considered a novel food and therefore CBD and foodstuffs containing it cannot be marketed without prior assessment and authorisation by the European Food Safety Authority (EFSA). The EFSA cannot currently outline its position on the safety of cannabidiol as a novel food due to data gaps and uncertainties about potential hazards related to CBD intake.

Since cannabis is still listed as a narcotic, the advertising is currently limited to the experimentation of medical cannabis only.

The unlawful transport, detention, offer, transfer, acquisition or use of narcotic substances is punishable by:

- 10 years' imprisonment and a fine of EUR7,500,000 if committed by natural persons; or
- 10 years' imprisonment and a fine of EUR37,500,000 (and various other sanctions that lead to the entity's dissolution) if committed by legal persons.

QUESTION TWO

What are the different types of CBD products and how are they defined?

In principle, pursuant to Article R. 5132-86-1 of the French Public Health Code (PHC), the culture, manufacture, transport, import, export, detention, offer, transfer, acquisition and use of cannabis (plant and resin) and THC (natural and synthetic) are prohibited.

On 13 January 2022, the French National Assembly dismissed a draft law related to the legalisation of the production, offer and use of cannabis over the French government's control.

Nonetheless, limited exceptions are established by legislation for medical and industrial use.

Medical use

Pursuant to the Decree No. 2022-194 dated of 17 February 2022, the pharmaceutical establishments and any establishments authorised by the French Health Agency (ANSM) to manufacture, import, and distribute active substance may be allowed to perform the above-mentioned acts, including, since 1st March 2022, the culture and production of cannabis, subject that the concerned product:

- Received an authorisation (i.e. Market Authorisation, Early Access Authorisation, Compassionate Access Authorisation or Import Authorisation); or
- Was registered as homeopathic drug; and
- Meet the requirements set by an upcoming Decree which will be published by the Health Ministry on a proposal from the Director of the ANSM and is manufactured as required by Article L. 5121-5 PHC or any equivalent internationally recognised standards to guarantee its quality, security and its medical purpose.

Cannabis plants may only be held and cultivated for



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Having practiced for 15+ years as counsel in business law for French and foreign companies or groups of all sizes established or active in France, Bruno Weil is your main contact for all matters relating to intellectual property, new technologies and IT. As such, he is involved in all advisory and litigation activities in these areas (in particular infringement of patents, trademarks, copyrights, license agreements and transfer of know-how).

His litigation has notably led him to successfully represent several leading companies listed in Germany and the United States before French courts, particularly in complex multi-jurisdictional patent infringement cases, with major challenges for companies concerned.

Bruno Weil also works with clients for business transformation operations or on acquisition files. The same applies to litigation for all types of cases related

to business life. Its first objective is to develop the best strategy to ensure the interests of our clients prevail, both in demand and in defence.

Since its establishment in 1974 WEIL & ASSOCIÉS is a law firm dedicated to the service of international companies.

Our firm is devoted to assist companies, international or small and medium-sized, in their commercial or industrial activities in France or abroad through proactive legal advice as well as by the defence of our clients before courts and arbitral tribunals.

WEIL & ASSOCIÉS has lawyers admitted at bars in France, Germany and the US at the same time. Our involvement in the advice to and representation of international clients implies that all lawyers write and speak fluently German, French and English. Over time, we have also expanded into countries such as Japan, Korea and China.

Our work is based on mutual trust with each client and international companies as well as small and medium-sized enterprises. Each client's activity, products and professional environment are carefully taken into consideration as our goal is to provide clients with tailor-made solutions that take account of the client's specific business interests.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

Legalisation of cannabis is a recurrent topic in France. The legal uncertainty regarding the marketing of CBD flowers has persisted for years. A decision by the Court of Justice of the European Union, dated 19 November 2020, invalidated France's prohibition to sell CBD products authorised in other European Member State where harmful effects on health could not be demonstrated, on the basis of the freedom of movement of goods.

In light of this decision and under the pressure from the

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ Make sure the CBD products you are manufacturing and selling or distributing are compliant with French and EU regulations.
- ✓ If you are distributing your CBD products in countries outside France or in other EU Member State, get clarification on whether or not these products can be imported to France.
- ✓ If you are growing or cultivating CBD plants, make sure the seeds are certified and listed in the official catalogue, and the authorisation to grow the plants is obtained.
- ✓ Check that the advertisements made for products containing CBD do not create any confusion with cannabis and do not make any therapeutic claim.
- ✓ CBD legislation changes regularly, ask advice from a lawyer on the legal impact on your business.

“CBD stores and tobaccos had to stop selling raw flower and leaves from the beginning of this year.”

changes underway in other European countries, legalisation of cannabis has reached a new milestone in France.

On 23 June 2021, the French Supreme Court (“Cour de cassation”) stated that flowers legally produced in a European country cannot be banned in France.

A Decree dated 30th December 2021 extended the authorisation for cultivation, import, export, and industrial use of certain varieties of cannabis with a THC content of less than 0,3% in all parts of the plant.

However, and as mentioned in question 1, the sale to consumers of raw flowers or leaves is still prohibited. Many French association officially and publicly opposed these restrictions and requested the Highest French Administrative Court (“Conseil d’Etat”) to cancel the further prohibition applicable to raw flowers and leaves. On 24 January 2022, the Conseil d’Etat decided to suspend the enforcement of the decree provisions related to the prohibition of sales to consumers, possession, and consumption of flowers and leaves in their raw state. The final decision has not been issued yet. Therefore, CBD stores and tobaccos had to stop selling raw flower and leaves from the beginning of this year.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

The main problem for producers and suppliers of CBD products is that the question whether the product can be placed on the market legally cannot be answered simply with yes or no. First, the correct legal classification of the product is essential. Depending on whether the products may be considered as narcotics, medicinal products, medical devices, foods or cosmetics, there are different regulatory requirements.

The first and biggest barrier to overcome is the German Narcotics Act ("Betäubungsmittelgesetz" – BtMG), which determines the national legal framework for the marketability of cannabis and CBD products. According to its sect. 3 para. 1 no. 1 the intercourse with narcotics requires permission. Thus, any unauthorized handling of narcotics is punishable by law. While cannabis is a narcotic according to the BtMG, this does not apply to CBD. However, foods containing CBD are currently non-marketable because CBD is considered a so-called "novel food" which requires approval. Since CBD has not yet been approved as a novel food, such products therefore cannot be legally placed on the market.

Furthermore, the requirements of the Health Claim Regulation (EU 1924/2006) must be observed, when the CBD product is advertised with nutrition or health claims. As an example, claims such as "high in Omega-3", "may help to relax" or "helps with insomnia, migraine etc." might be considered as nutrition or health claims. Health claims are only permitted if they are approved in accordance with the Regulation and included in the list of authorised claims. However, this list does not include a specific health claim on CBD products. Therefore, claiming that the CBD product may be beneficial for someone's health, may be problematic.

"While cannabis is a narcotic according to the BtMG, this does not apply to CBD."

QUESTION TWO

What are the different types of CBD products and how are they defined?

We mainly see the following CBD products on the German market: medicinal products, food, including food supplements, and cosmetics.

Medicinal products are all substances or preparations thereof, which are either intended to cure, ease or prevent human diseases or to restore, remediate or affect physiological functions by a pharmacological, immunological or metabolic effect or to make a diagnosis. Please be aware that if an informed consumer is given the impression that a product, in view of its presentation, is intended as having properties for the cure or prevention of human disease, it is also considered a medicinal product, namely a so called "medicinal product by presentation" (in German: "Präsentationsarzneimittel"). Also such a medicinal product requires marketing authorization.

Foods are all substances intended to be eaten. Food



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Margret Knitter LL.M. is a partner of the German law firm SKW Schwarz and a Certified Expert for IP. Additionally, she is head of the Cannabis Practice Group at SKW Schwarz. She advises her clients in all matters of intellectual property and competition law. This includes not only strategic advice but also legal disputes. Her practice focuses on the development and defense of trademark and design portfolios, border seizure proceedings and advice on developing marketing campaigns. She advises on labelling obligations, packaging design and regulatory questions, in particular in the Life Sciences, Foodstuffs and Cannabis industries.

She regularly holds lectures at seminars and conferences. She is a member of the International Trademark Association (INTA), INTA Non-Traditional-Trademarks Committee, Pharmaceutical Trade Marks Group (PTMG) and of the board of the Branded Content Marketing Association (BCMA) for the DACH region. She is the author of numerous professional articles and other publications, e.g. 10 Q&A's related to Medical Cannabis in Germany.

Margret is recognized as a leading lawyer in Who's Who Legal 2022 in the

supplements are also considered foods. When classifying a product as a food, it should be noted that a significant consumption of CBD in the European Union before May 15, 1997 has not been documented, with the consequence that CBD is considered a so called "novel food". Several applications for the approval of a novel food are pending. Until its approval, the distribution of food containing CBD is currently not legal in the EU.

Cosmetics are for cleansing and caring purposes only. Difficulties arise in distinguishing them from medicinal products if they have a certain pharmacological effect, and from foodstuffs if they are to be absorbed through the oral mucosa.



category "Trademarks". IP Stars ranked Margret among the Top 250 Women in IP and among the Trade Mark Stars 2022. The Legal 500 (2022) recommends her in the category "Trademarks". Margret is a "Global Leader" and Gold Tier recommended lawyer in the 2022 edition of World Trademark Review.

The law firm **SKW Schwarz** is one of the leading commercial law firms in Germany and is known for its focus on the legal issues of the future. In order to meet the requirements of the growing market for medical cannabis and CBD products, the law firm has established its own focus group. Experts from IP, regulatory, corporate/M&A, commercial and distribution law as well as public procurement law provide comprehensive advice to the industry on all legal and regulatory issues.

Our team of experienced lawyers support clients in the following key areas:

- Regulatory check
- Protection of intellectual property rights
- Licensing your cannabis products
- Establishing distribution and supply chains
- Obtaining licenses
- Venture Capital, Private Equity and M&A transactions

SKW Schwarz is an independent full-service law firm. With over 300 team members, including more than 130 lawyers, we advise in all relevant areas of business law. And we always think a few steps ahead. We analyze and create clarity. Today and tomorrow.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

Medical cannabis has only been legal since 2017 in Germany. Recreational cannabis is still illegal in Germany. However, the German coalition partners have agreed to introduce legislative proposals, which will govern how the intention "to legalize cannabis for recreational use" will be implemented.

The regulatory requirements differ depending on the legal

TOP TIPS

On ensuring commercial success in your jurisdiction

✓ **Make sure that your CBD product does not seem like a medicinal product.** If a product whose presentation or advertising gives the impression that the product is intended (not necessarily appropriate) for the cure, mitigation or prevention of disease in the sense of a medicinal product, under German law it is classified as a medicinal product. Consequently, the product may not be placed on the market without a marketing authorization.

✓ **Do not use health claims for your CBD products.** CBD is not included in the list of authorised claims of the Health Claim Regulation. Therefore, claiming that the CBD product may be beneficial for health may not be permitted.

✓ **Establish an attractive brand.** The registration of cannabis trademarks is generally permitted in Germany and the European Union. However, in the past the Trademark Offices refused several trademark applications because it was held that the applications are contrary to public policy or morality. As case law shows, this is especially assumed if a trademark creates the impression that the use of cannabis is being glorified.

classification of the relevant product. The question of whether and how a product containing CBD can be legally placed on the market is essentially governed by the provisions of the BtMG, the Medicinal Products Act ("Arzneimittelgesetz" – AMG), if applicable the Medical Device Regulation (MDR) or the European and national regulations on foodstuffs and cosmetics.

With regard to the regulatory status of narcotics, reference is made to what was mentioned under item 1.

Products that qualify as finished medicinal products within the meaning of the AMG are generally subject to marketing authorization (see sect. 21 AMG). Without marketing authorization, finished medicinal products cannot be marketed. Any distribution without authorization is punishable by law. The authorization must be obtained from the BfArM or the European Medicines Agency (EMA). Furthermore, the manufacturer of the product requires inter alia a manufacturing authorization according to sect. 13 para. 1 sent. 1 AMG. This does not apply for extemporaneous mixtures prepared in pharmacies. The preparation of extemporaneous mixtures is subject to the Pharmacy Practice Order (Apothekenbetriebsordnung - ApBetrO).

If the product is a food, the placing on the market is governed by directly applicable Community Law, namely the Regulation (EC) No. 178/2002, the so-called General Food Law Regulation (Lebensmittelverordnung), as well as by some national German regulations, inter alia the German Food and Feed Code (Lebens- und Futtermittelgesetzbuch – LFGB), the Food Supplement Regulation (Nahrungsmittelergänzungsverordnung – NemV) as well as the European Regulation on Novel Foods (Neuartige Lebensmittel-Verordnung – NLV).

If the product is a cosmetic, the Regulation (EU) No 655/2013 and the Cosmetics Regulation (Kosmetikverordnung) is applicable.

CBD, an approach from a Greek legal (and more) point of view...

Local production and distribution

Cannabidiol, commonly known as CBD, is a non-psychoactive chemical compound from the Cannabis Sativa L plant. In Greece, the cultivation of industrial cannabis, also known as hemp, which contains less than 0.2% of psychoactive cannabinoid THC, became lawful in 2016 by virtue of the Joint Ministerial Decree No 1750/39224 (Government Gazette B 929/2016). Since then, the cultivation, production, and sale of such industrial cannabis (CBD) products have increased, with almost 3,300 cultivated acres in 2019, despite the relatively new market. Consequently, the production and sale of CBD products is very attractive considering that Greece offers the appropriate conditions for cultivation. With Greece's favorable climate with its prolonged sunshine, fertile soil and geographical location, all are ideal conditions when it comes to growing cannabis, either conventional or organic, in open fields and also in greenhouses with controlled environmental factors. Regarding the storage, security and delivery of raw materials and finished CBD products, Greece's regulatory framework is exhaustively analytical regarding the step-by-step procedures to be followed with the cultivation of CBD, with further restrictions on medicinal cannabis. Promotion/advertising of products containing CBD is allowed, whereas advertising of cannabis-related medicinal products is prohibited.

The hidden secrets of CBD

As to the status of the Greek CBD market, the most popular CBD product is CBD oil, which is found in various manufactured goods. However, CBD products are not limited to oils. There are numerous product codes, close to 70 in total, including capsules, concentrates, topicals, sprays, vapes, plasters, candles, crystals, and a variety of edibles. Each one is defined either by its usage, e.g., if one can spray it into the mouth, apply it on different body areas, or even inhaling it, or by its concentration of the compound CBD. Hemp extracts (CBD) represent a major area of interest for the health and wellness industry, due to its well-known pharmaceutical uses that aim to alleviate different kind of health problems, such as chronic pain, acne, psoriasis, anxiety and more. Apart from CBD, cannabis is prohibited in Greece for its recreational use, as it is still considered a narcotic drug, with addictive substances. But by virtue of the Law 4523/2018 the production, possession, transportation, storage, supply of raw material and substances of the cannabis species Cannabis Sativa L, containing more than 0.2% of THC, is legal, under the condition of either supplying the state monopoly for further distribution to the medical sector/pharmacies, for patients' health needs, or exporting these products.

CBD's most substantial legal aspects

The cannabis industry in Greece is considered to be one of the fastest growing sectors. Cannabis investments, worth millions of euros, are taking off. Those who have a keen interest in either cultivating, producing, or processing CBD, have to submit the appropriate documentation (indicatively property documentation regarding land dedicated to the cultivation, greenhouse applicable permit, copy of criminal record, nomination of an authorized tax and procedural representative in case the applicant is a foreign entity/individual) and obtain specific licenses and certifications (facilities approval, authorization to operate).

Entrepreneurs wishing to set up companies in Greece can



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Manolis Eglezos is managing partner at Manolis Eglezos and Associates Law Firm in Greece. He is an expert in Commercial, Corporate, Maritime Law and has a broad knowledge of GDPR since its introduction, and is a certified DPO. He advises groups and companies, adopting a commercial perspective when providing legal services. He focuses on credit and securities, corporate (including M&As) tourism, shipping, industry sector and GDPR compliance, both consulting and litigating. His approach goes beyond the simple legal point of view, as it also considers market parameters as well as social factors, a combination that leads to an efficient and optimum result. He holds an LLM and an MSc degree, writes legal (and non-legal) articles and occasionally lectures on issues that fall within his specialization. He speaks Greek, English and Spanish.

“As to the status of the Greek CBD market, the most popular CBD product is CBD oil, which is found in various manufactured goods. However, CBD products are not limited



Manolis Eglezos and Associates Law Firm is based in Piraeus, Athens, Greece. It specializes in Maritime, Commercial, Corporate law (including complex transactions, tax planning, M&As etc.), Real Estate, Visa granting schemes and GDPR. The firm understands the need for reliable legal advice within tight deadlines and is committed to providing this kind of assistance. We aim to achieve the commercial goals of the client, taking into account the existing difficulties, and ultimately reaching the solution that meets their commercial objectives within the regulatory framework. A network of affiliated offices in Greece and abroad allows the firm to accommodate the international needs of legal entities, entrusting to it their legal representation. The firm's attorneys are able to provide effective advice on issues arising through their academic training and extensive experience. Manolis Eglezos and Associates advises the largest Tourism organization worldwide, Greek and Chinese banks, Paints Industry Multinational Leader, Maritime Groups, Piraeus Chamber for Small and Medium Sized Companies, both consulting and litigating, locally and internationally.

to oils. There are numerous product codes, close to 70 in total, including capsules, concentrates, topicals, sprays, vapes, plasters, candles, crystals, and a variety of edibles.”

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ **Greece as an entrepreneurial hub.** Its position among the 11 fastest countries in terms of company formation, along with an excellent climate and a booming economy, makes the country the ideal destination for an entrepreneur. The one-stop-service for companies' incorporation is an innovation, allowing the setting up of a company in a couple of days.
- ✓ **Business Opportunities and Market's gaps.** The pharmaceutical Industry, as well as food and cosmetics' sectors, are booming in Greece, especially after the introduction and legalization of CBD. Consulting experts in each area will ensure the successful operation and establishment of a business. In a more general sense, it is indispensable to conduct in-depth research to identify market gaps and investment opportunities.
- ✓ **International trade.** Exports are important for the Greek economy and the strategic location of Greece is beneficial for international trade with many countries. In order to make a significant amount of profit, businesses should seek the appropriate combinations of products and countries of destination. Cannabis products have a local and international market.

do so without delay. Greece is in the 11 top countries regarding the speed in which a company formation can be adopted. It is advisable to have a tax expert and an investment consultant familiar with the applicable investments and taxation's laws, indicating possible applicable subsidies, and assisting in obtaining licenses required; particularly, the strict conditions required by law concerning the size and attributes of the land to be used, the process of obtaining a license according to the nature of the activity (e.g., CBD or pharmaceutical cannabis production plant and its operation). Whilst CBD licensing is a simpler procedure, obtaining a pharmaceutical one contains more stages and is subject to more controls. Even if the above may sound bureaucratic, the authorities involved are making a significant effort to speed up the process and open the way to the expansion of the cannabis industry in Greece. The up-and-coming projects concerning cultivation, the processing of raw materials and the production of the final product, both for industrial and medicinal cannabis, are going to securely boost not only Greece's fast-evolving economy but related international business as well.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

The status of current CBD regulation is as described below, and if CBD products (including raw materials, works-in-progress, and semi-finished products) handled in Japan are even partially derived from regulated parts of the cannabis plant (parts other than mature stems or seeds), or contain THC even in trace amounts, there is a risk that those involved in the production or sale thereof will be punished, or if not punished, will be forced to discontinue or recall the products. (It is expected that the above risks will be reduced by the planned revisions to the laws and regulations in the future.)

Furthermore, CBD products may be subject to strict regulations as pharmaceuticals, depending on the future response of the Ministry of Health, Labor and Welfare (MHLW).

In Japan, the manufacture and sale of pharmaceutical products is strictly regulated by law, but products containing substances listed in the List of Ingredients (Raw Materials) Used Exclusively as Pharmaceutical Products set forth by the MHLW fall under the category of pharmaceutical product and are subject to strict regulations as pharmaceuticals regardless of whether advertised or sold with the appearance of a pharmaceutical product (e.g., with an indication of medicinal efficacy or dosage, or a pharmaceutical-like shape or container, etc.).

Currently, CBD is not included in the list, but it cannot be said that there is no possibility that it will be added in the future, and if it is added there is a risk domestic production and sales of non-pharmaceutical CBD products will be severely restricted.

“By law, cosmetics are defined as “something intended to be used by rubbing, spraying or similar methods on the body to cleanse, beautify, enhance attractiveness, change appearance, or keep the skin or hair healthy, and which has a mild effect on the human body.”

QUESTION TWO

What are the different types of CBD products and how are they defined?

There is nothing in law defining the type and classification of CBD products.

As for CBD products currently distributed in Japan, it seems that there are many products corresponding to cosmetics and



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In 1983, Kenji Kuroda passed the National Bar Examination at 20 years of age. After developing practical experience as an attorney, he attended law school in China (Fudan University Faculty of Law, Advanced Study Course), Denmark and the United States (Duke University Law School). Following his admission to the bar in New York in the United States, Mr. Kuroda founded Kuroda Law Offices and Kuroda Patent Offices in 1995, later establishing our Shanghai office in 2004 and opening the first Japanese law firm in Taiwan in 2009, specializing in Chinese law, information technology and intellectual property, with the aim of providing strategies tailored to the customer’s needs.

In its ranking of leading attorneys, Nihon Keizai Shimbun selected Mr. Kuroda

second in the international law section and eighth in the international law section (December 19, 2012). In addition, Nikkei Business selected Mr. Kuroda third in the international matters section of its business attorneys ranking (December 22, 2014).

KLO provides all types of legal services (such as labor law, corporate law, IP law, fraud surveys and dispute resolution) to Japanese subsidiaries of foreign companies. With offices in Shanghai and Taipei, and the Shanghai and Beijing branches of our affiliate, KLO Consulting (Shanghai) Co., Ltd., we provide comprehensive service locally.

Furthermore, we offer advice to maximize client profits, such as ways to effectively use IP rights, strategic planning to design and develop new products and services without infringing third party rights, and methods to prevent all manner of litigation and disputes. We also have ample experience with litigation in new fields (such as LEDs).

By using the experience and expertise, mobility and organizational abilities we have cultivated over the years to meet the ever-changing needs of our clients and the market, we strive to continue providing the best legal services to our clients in new and innovating fields on the world stage.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

The current regulatory status in Japan is as follows, and adequate framework is not yet in place.

CBD is not regulated as a substance.

However, the current Cannabis Control Act regulates cannabis products by focusing on the part of the cannabis plant rather than the ingredients contained therein, so almost all handling (including import/export, possession, giving and receiving; this also includes application and reception for pharmaceutical products) of CBD products derived from the cannabis plant (including pharmaceuticals) is prohibited and offenders are punished, excepting those products where no

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✔ For cannabis-derived CBD products, it is important to establish a production line that can manufacture and supply products that can meet Japanese regulations. If this is difficult for technical or profitability reasons, it may be better to refrain from entering the Japanese market, at least under the current version of the Cannabis Control Act.
- ✔ CBD products must be completely THC-free. It’s important to use a trusted analysis institute to prove that your CBD product is THC-free. It is necessary to consider that THC content may not be detected correctly depending on the method, accuracy and other conditions of component analysis.
- ✔ Japanese laws and regulations that are applicable to CBD products (including various advertising regulations, labeling regulations, additive regulations, and licensing regulations) are strict and complicated. It is probably difficult to succeed in the Japanese market without entering into a partnership or cooperation with a reliable Japanese importer, distributor and/or consultant who is well-versed in CBD products.

regulated parts of the cannabis plant (parts other than mature stems or seeds) are used.

Therefore, no pharmaceuticals derived from the cannabis plant (including Epidiolex) have been approved in Japan yet.

On the other hand, CBD products (including cannabis-derived products and chemically synthesized products) are actually regulated by focusing exclusively on the THC content, which partially deviates from the regulations set forth in law.

Specifically, when importing CBD products into Japan, documents showing not only that regulated parts of the cannabis plant are not used (or that they are chemically synthesized products), but the component analysis results for THC content must be submitted to the regulatory agency. In addition, the MHLW has announced that if THC is detected even in trace amounts in CBD products distributed in Japan, the product will be suspected of violating the Cannabis Control Act. In that case, the product may be forcibly discontinued or recalled, depending on the circumstances.

Currently, the MHLW is considering revisions to the relevant laws and regulations in view of promoting the appropriate use of cannabis and CBD, including lifting of the ban on medical cannabis and introducing cannabis regulations focusing on its component (THC) (instead of the part of the cannabis plant), and it is expected that the law will be revised next year at the earliest.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

Malta has now de-criminalised the personal use of cannabis and permits growth for personal use of (a max of 4) cannabis sativa plants, to harvest weed, as well as the commercial production and importation of non THC cannabis (known as hemp) for medicinal use.

The regime in Malta is one of the most progressive in the world and is likely to develop. This will give rise to new commercial opportunities. The risk is that some commercial operators will try to jump the gun and do more than the law allows at any given time.

Otherwise, the risk of penalty and sanction will be low for any individual or entity observing and adhering to the licensing requirements laid down in the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta), and of the law itself.

Thus, a licensed operator must adhere to detailed regulations on quality-assurance, security, monitoring of the production facility, import and export, storage and possession, reporting obligations, and advertisement.

The storage and possession of the harvest from local cultivation must satisfy the requirements set out in the relevant legislation.

Each finished unit product pack shall display the respective serial number, in a tamper-evident manner, as established by the regulatory authority, prior to any transactions related to the product.

The advertisement of cannabis to the public as a treatment for any medical condition is, in terms of the Medicines Authority General Guidelines on the Production of cannabis for medicinal and research purposes expressly prohibited.

Advertising the product in Malta would, therefore, appear to be risky and unadvisable. There are, however, (EU) Single Market issues to take into account for the Court of Justice of the European Union, which interprets EU law, has ruled (C-663-18) that: No Member State can preclude the advertisement of a CBD product lawfully produced in another Member State in view of the fact that CBD is not a 'drug' within the meaning of the Single Convention of the United Nations, due to its lack of 'psychoactive ingredient'.

QUESTION TWO

What are the different types of CBD products and how are they defined?

The law does not make a distinction between CBD products themselves (although all require a prescription in order to be administered medically).

The main legal distinction is between THC and CBD, and this is made in the penal code: Cannabis is defined in the Dangerous Drugs Ordinance (Chapter 101) as "the inflorescence and leaves of any plant of the genus Cannabis and includes any resin obtained from the said plant and any preparations derived from the said plant".

This definition excludes seeds or cannabinoid products that have as much as or less than zero point two (0.2) percent of tetrahydrocannabinol (THC).

As long as the cannabinoid product has a THC content of not more than 0.2%, then it is not subject to the criminal sanctions found in the Dangerous Drugs Ordinance.



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Kris Scicluna joined AE in 2012 and was admitted to partnership in 2018, leading a team of other litigators who have deep experience in tax litigation, commercial and civil law disputes.

Kris maintains an uncommon profile as a litigator and beneath his urbane manner is a tenacity that his clients value and seek. In his insolvency work, in different major cases, he has been crucial and effective when representing both creditors as well as debtors.

He is a member of the Chamber of Advocates and holds a certificate in 'Trust Law & Administration' (2011) and 'An Introduction to the Virtual Financial Asset Act' (2018) from the Institute of Financial Service Practitioners.

Learn more about the team here <https://ae.com.mt/about>

The distinction is not easy to make:

- It can be very difficult to distinguish CBD flowers (commonly known as hemp flowers) from THC flowers (commonly known as weed).
- The CBD hemp flower is so similar in appearance to its 'cousin' THC that the police, in Malta and overseas, have often seized "marijuana" only to find that it was perfectly legal hemp. Therefore, when it comes to the transport and storage of CBD products, it is necessary to provide evidence that the product is actually a CBD product (i.e. <0.2% THC content) since THC products are much more heavily regulated and are not commercially trade-able in the free and open market.

“Agius’ lawyers, on the other hand, say that the flower in question contained less than 0.2% THC and is a CBD ‘product’, much like CBD oil, shampoo, or facial cream, which can all be sold without restrictions.”

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ Keep an eye on the law and the governing bodies it establishes. Now that the legislator has embraced decriminalization, this area will continue to develop and opportunities for commercial enterprise may abound.
- ✓ The Authority for the responsible use of cannabis has not yet started issuing any guidelines. When it does it ought to set out how user associations, the so-called "Weed Clubs", will be permitted to function and whether membership fees can be levied.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

The cannabis legal framework in Malta is now one of the most progressive within the EU and beyond.

That said, the situation created by the new law is not yet satisfactory and requires refinement. There is still too much scope for conflict between the obvious spirit of the law and the actual enforcement on the ground:

There still is uncertainty amongst public authorities, like the police, over what legally constitutes legal cannabis. Indeed, a petition has recently been presented to the Parliament of Malta urging lawmakers to amend Malta's year-old cannabis laws to explicitly exclude forms of cannabis that do not provide any 'high' from the threat of prosecution.

The situation came to a head with the arraignment last March (2022) of a medical doctor, Andrew Agius, who stands accused of importing and trafficking the drug after police seized CBD cannabis flowers from his clinic, a pain treatment centre, last February.

The case revolves around the interpretation of the abovementioned 2021 definition of CBD 'product' in the penal code.

When Agius was charged in court, prosecutors argued that the CBD flower they seized from his clinic is a narcotic and subject to seizure and prosecution.

Agius' lawyers, on the other hand, say that the flower in question contained less than 0.2% THC and is a CBD 'product', much like CBD oil, shampoo, or facial cream, which can all be sold without restrictions.

The situation has led the petitioners to ask MPs to fix this legislative anomaly by explicitly excluding all CBD products, including flowers, leaves and resin, from the scope of criminal prosecution and to start a public discussion about business and agricultural opportunities concerning CBD and hemp products. Petitioners also refer to classifying CBD as a 'novel food', something the European Commission is in the process of doing after following the aforementioned CJEU judgement.

QUESTION ONE

What are the different types of CBD products and how are they defined?

The clients I assist sell CBD products that usually belong to one of four categories: food supplements, cosmetics, medicines or food. What I have noticed is that the trade in CBD products qualifying as food supplements is growing. This is not surprising. The CBD products that qualify as food supplements offer the customer the opportunity to benefit from the health advantages associated with the intake of CBD. Because food supplements are available in all shapes and sizes, there is always a form of administration that suits the customer.

QUESTION TWO

What are the risks of CBD production and sales in your jurisdiction?

CBD sales

A first risk that may arise concerns the (incorrect) way in which the effects of the CBD products are described. It happens regularly that, when marketing CBD products, the client mentions the alleged health benefits of using the product. This is very understandable. After all, the reason that the sales of CBD products have increased in recent years is the health benefits that are associated with the intake of CBD products. However, the problem is that as soon as a client formulates the benefits of the use in such a way that it concerns a possible health claim or a medical claim, in some cases the client needs a license to be able to make such a claim. If the client does not have such a license, this may have serious legal implications.

A second risk that may arise involves the tetrahydrocannabinol (THC) content in the CBD products. The Dutch Inspectorate for Health Care and Youth (known as the IGJ in short) has stated that there is an upper threshold for the content of THC in CBD containing products of 0.05%. CBD products containing less than 0.05% THC can be marketed without any reference to THC. The IGJ then considers the THC to be a contaminant that entered the product during purification.

CBD products containing more than 0.05% THC are formally subject to the Dutch Opium Law and may not be marketed as a commodity!

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

The ever-changing legal status of CBD

In light of the current discussion about whether or not (a product containing) CBD is considered to be a novel food under the EU Novel Food Regulation (Regulation 2015/2283), I have received many questions regarding the legal status of CBD products in the Netherlands.

With regard to the legal status and the risks for marketing resulting from the applicability of the Novel Food Regulation, it is important to note that a policy of tolerance applies with respect to CBD products in the Netherlands. In practice, law enforcement in the Netherlands is focused on the use of unauthorized medical claims. All the more reason to seek legal



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John Wolfs is founder and managing partner of the Dutch law firm Wolfs Advocaten. Prior to starting his own law firm almost 20 years ago, John Wolfs has worked for several well-respected law firms in Washington DC as well as in Rotterdam. His practice focuses on international trade & transport law, corporate law, customs law, (international) commercial law and insurance law.

In addition, John Wolfs is an expert on the field of cannabis law. In this regard, John Wolfs assists entrepreneurs in setting up companies in the Netherlands trading in cannabis based products, advises on the legal implications of the trade and litigates where necessary.

Jolanda de Jong is one of the lawyers of the Dutch law firm Wolfs Advocaten. Prior to working for Wolfs Advocaten, Jolanda de Jong has worked for several (international) organisations whereby she gained ample experience in the field of insurance law as well as (international) health law. In addition, Jolanda de Jong is working closely together with John Wolfs on cases involving cannabis law, another area of expertise.

Wolfs Advocaten B.V. is based in Maastricht, Amsterdam and Venlo. Wolfs Advocaten offers legal solutions for entrepreneurs in the Netherlands and abroad. The firm covers all areas of law and specializes in advising and litigating in international trade & transport law, corporate law, customs law, (international) commercial law, insurance law and, of course, cannabis law.

advice prior to making any claims about your CBD products.

Despite the policy of tolerance, there are nevertheless certain risks associated with the marketing of CBD products.

In the Netherlands, the Dutch Food and Consumer Authority (known as the NVWA in short) is one of the supervisory authorities with regard to the compliance of Dutch food laws and European regulations with the aim of safeguarding human health. The NVWA has various enforcement instruments at its disposal. Depending on the seriousness of the violation, it can take corrective and sanctioning measures, including fines, penalties and seizure of products.

In the Dutch Manual on Novel Foods (published by the NVWA) it is stated that if the NVWA determines that novel foods are traded that are not included in the Union list an administrative fine will, in principle, be imposed.

Difficulties for entrepreneurs

In the Netherlands, the main problem for entrepreneurs wishing to start a company that is involved in the trade of CBD involves practical issues like opening up a bank account. It is my experience that Dutch banks are somewhat reluctant to be of service after discovering the purpose of a CBD related business for opening a bank account. However, given the increasing popularity of CBD products as well as the increasing resistance regarding the qualification of (products containing) CBD as a novel food, it is my belief that in the foreseeable future this will no longer be an issue.

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ Choose the type of CBD products you wish to trade in carefully. Depending on the type of CBD-product, different Dutch regulations apply.
- ✓ Choose your words wisely when advertising your CBD products.
- ✓ The regulations regarding CBD are constantly changing. Therefore, it is important to seek legal advice before getting involved in this business.

Feel free to contact me or one of my specialized colleagues like Jolanda de Jong.

“Given the increasing popularity of CBD-products as well as the increasing resistance regarding the qualification of (products containing) CBD as a novel food, it is my belief that in the foreseeable future this will no longer be an issue.”

In Spain there is no specific law regulating the production, marketing, import, export and consumption of CBD products, thus the performance of such activities in Spain is subject to the provisions of current national laws and the interpretation of international conventions and applicable court decisions (jurisprudence).

The cultivation of the cannabis plant, regardless of its THC content, is subject to the regulations of the 1961 Single Convention. This was signed and ratified by Spain on 3 February 1966 in the Law 17/1967 of 8 April 1967, which updates the current regulations on narcotic drugs, adapting them to the provisions of the Single Convention, and the Order of 7 May 1963, which lays down the rules for the cultivation of medicinal plants related to narcotic drugs.

Cannabis is generally considered to be a narcotic drug and is included in Schedule I of the Single Convention. Consequently, use is controlled and the cultivation of the cannabis plant is exclusively for industrial (fibre and seeds) or horticultural purposes, as established in Article 28 of the Single Convention and Article 9 of Law 17/1967.

“The interest in hemp and its expansion in Spain has led the Ministry of Agriculture, Fisheries and Food (MAPA) to release an informative note on the main conditioning factors of this agricultural activity in the country, especially in relation to the rise of cannabidiol (CBD).”

As a consequence of the above, the cultivation of the cannabis plant is very restricted and requires prior authorization from the Spanish Agency for Medicines and Health Products (AEMPS)¹ unless the crops are intended for industrial purposes (exclusively for obtaining fibre, grain and/or seed) provided that they are free of the active narcotic substance. That is to say that the European Union limit of 0.2 tetrahydrocannabinol (THC) is not exceeded until January 1, 2023 and of 0.3 after that date.

For this percentage not to be exceeded, the European Union requires that to be able to cultivate industrial hemp, certified seeds must be registered in the common catalogue of varieties of agricultural plant species of the European Union, or varieties with a Provisional Marketing Authorisation (PMA), according to the Commission Decision 2004/842/EC of 1 December 2004, whose main characteristic is that the THC concentration is limited to 0.2%. As established in the EU Regulation 2021/2115 of December 2, 2021.

Therefore, the production, manufacture, export, import, distribution, trade, use and possession of cannabis should be limited, as stated in Article 4(c) of the Single Convention,



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Juan joined Grupo Gispert in September 2017. He graduated in law from the University of Barcelona, and has broad experience in advising national and international companies. His specialism is in Corporate Law and M&A (acquisition of companies, joint ventures, mergers and restructuring operations), business contracts (sale and purchase, supply of products or services, distribution or agency contracts, franchise, etc.) and Real Estate Law.

Likewise, he is Secretary of the Board of Directors of many companies providing legal advice and compliance. He is also a member of the Barcelona's Bar Association since 2001.

Academic Background

- Law degree (University of Barcelona).
- Master's program of International Business Law from the ESADE Business and Law School.
- Postgraduate in Corporate Law from the Barcelona Bar Association.
- Course of accountancy for lawyers at the Abat Oliba University.

to medical and scientific purposes, and its use for any other purpose is prohibited.

The interest in hemp and its expansion in Spain has led the Ministry of Agriculture, Fisheries and Food (MAPA) to release an informative note on the main conditioning factors of this agricultural activity in the country, especially in relation to the rise of cannabidiol (CBD).

This note differentiates between those crops for which it is not necessary to obtain authorisation from the AEMPS (Agencia Española del Medicamento y Productos Sanitarios) and which are intended for the industrial production of fibre, grain and seed with a tetrahydrocannabinol (THC) content of 0.2% or less,



Founded in 1940, Grupo Gispert provides legal advice at national and international level, to businesses and individuals from its offices in Barcelona and Madrid.

To understand the global needs of the client beyond the hired service, the firm has set up a multidisciplinary team of high-qualified lawyers and economists that design the best strategies to help our clients reach their goals. The team consists of more than 35 professionals whose target is reaching excellence service provided.

In Grupo Gispert we believe that every client is a new challenge to prove our value and earn their trust. We also believe that progressing together and advise the client in all the phases of its business makes us a better firm. We know that these goals may be achieved only with the effort and commitment of every member of our team.

and those crops for research and/or medical purposes that do require authorisation from the AEMPS.

As a consequence of the illegal use of the cannabis plant as it is considered a narcotic drug in Spain, it is only possible to extract CBD from the non-controlled parts of the plant; that is, from the seeds or from the leaves not attached to the tops and it is not permitted to extract CBD from the flower or bud of the plant.

Having analysed the legal status of cannabis, it is necessary to determine and analyse which uses of the cannabinoid called Cannabidiol (CBD) are permitted in Spain, especially in food, food supplements and cosmetics.

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ The lack of clear regulation means that there are still grey areas. A detailed analysis of the business to be carried out in Spain would be necessary to be able to make a correct interpretation of each assumption and its possible legal fit.
- ✓ The legal landscape in Spain could change shortly and it is important be updated regularly.

In Spain, natural or synthetic substances included in Schedule I and II of the Single Convention are considered to be narcotic drugs.

CBD is listed as a novel food in the European Union. As CBD is classified as a non-authorized novel food in the European Union, the manufacture and marketing of foodstuffs containing CBD for human consumption is prohibited in Spain.

CBD oil and any other product containing CBD cannot be used as a food supplement or marketed as such in Spain or Europe as it is classified as a novel food.

The manufacture of cosmetics with CBD extracted from the cannabis flower is not allowed in Spain as the AEPMS considers that products with CBD obtained as cannabis extract are included in Schedule I. In Spain it is only possible to manufacture cosmetics with CBD from the non-controlled parts of the cannabis plant, that is, the seeds and leaves.

The legality of production in Spain of cosmetics with CBD extracted from the cannabis flower imported from a member state of the European Union where the extraction is legal and its traceability can be demonstrated could be sustained.

Cosmetics containing CBD extracted from the controlled parts of the cannabis plant can be marketed in Spain provided that the CBD has been legally produced in another European Union member state and its traceability can be demonstrated.

Products containing CBD, consisting of gummies and waters, cannot be manufactured and marketed in Spain as foodstuffs, as CBD is considered a novel food, unless they have been authorized as novel food.

Skin care products with CBD could be manufactured and marketed in Spain, as long as their THC content is lower than 0.2%. The CBD extraction comes from the non-controlled part of the hemp plant (leaves and seeds) and the product is for topical application.

The topical CBD products manufactured in Spain, understood as cosmetic, could be considered legal if the CBD extraction were to come from the non-controlled parts of the cannabis plant, that is, the seeds or the leaves not attached to the tops.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

The risk of non-compliance with state and local laws is one of the biggest hazards when it comes to starting a marijuana-related business. Marijuana products (including CBD) cannot be advertised as having medical or therapeutic benefits or contain claims that the product is safe. Though “[a] Marijuana Establishment may engage in reasonable Advertising practices that are not otherwise prohibited in 935 CMR 500.105(4) (b) that do not jeopardize the public health, welfare or safety of the general public or promote the diversion of Marijuana or Marijuana use in individuals younger than 21 years old,” there are a host of restrictions on the content and manner of the advertising and labeling of cannabis products in the Commonwealth. For example, here is a non-exhaustive list of some of the advertisement restrictions marijuana businesses must be aware of and comply with: advertisements of marijuana products must contain a minimum of two printed warnings on their face, most advertisement channels are prohibited unless 85% or more of the advertising business’s consumer base is 21+, and advertisement content is restricted to things that are not deemed to appeal to people under the age of 21.

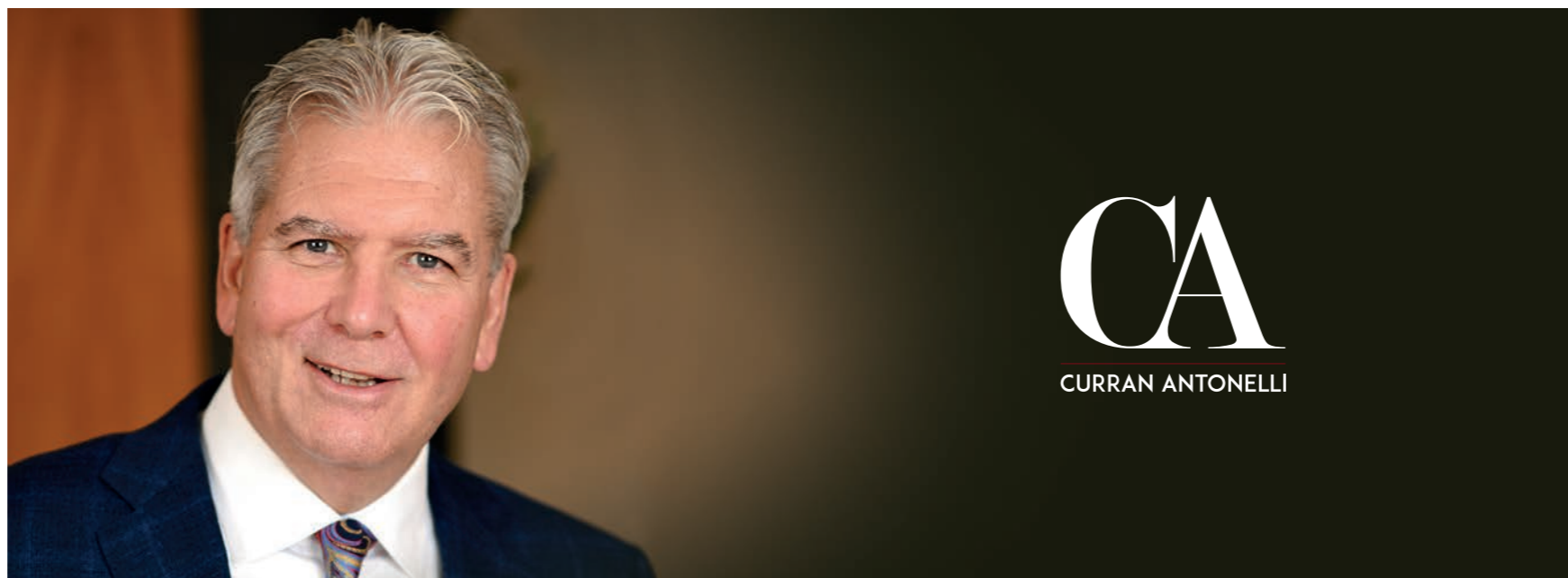
The storage and transportation of marijuana is likewise tightly regulated. The Cannabis Control Commission (CCC) of Massachusetts, the body that administers and implements marijuana laws in the Commonwealth, adopted regulations that outline a detailed process for the transportation of marijuana by dispensaries. This process requires coordination and monitoring to ensure multiple dispensary agents be present during the inventory and transportation of the marijuana, secure communication channels are available between the agents and the dispensary, and the marijuana product is weighed and tracked throughout the process. Additionally, when marijuana is transported it must be stored in temperature controlled conditions and in a container that prevents the contamination or deterioration of the product.

“The annual licensing fee for a cultivator varies based on the size of the cultivator but can reach up to \$50,000.”

QUESTION TWO

What are the different types of CBD products and how are they defined?

There are two types of CBD: hemp derived, and marijuana derived. Both hemp CBD and marijuana CBD are currently allowed in the state of Massachusetts. Hemp derived CBD contains less than .3% THC and is regulated by the Department of Agriculture Resources when sold wholesale. When hemp CBD is sold directly to consumers its labeling and advertising is governed by the FDA. The agency only allows the sale of non-food hemp CBD products without medicinal or therapeutic claims, until the product is reviewed and approved by the FDA. Health and wellness trends have started to incorporate the use



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Thom has developed his practice over the past three decades, focusing primarily on bankruptcy and insolvency proceedings. He often represent secured and unsecured creditors, committees of creditors, trustees and equity security holders in bankruptcy and insolvency proceedings as well as financial institutions and other lenders in out-of-court loan restructurings, assignments for the benefit of creditors, foreclosures, repossessions, and the sale of distressed assets and businesses.

Thom has experience in all facets of cross-border insolvencies and cross-border insolvency litigation. He is regularly engaged by private equity firms, governmental agencies and estate representatives to advise and counsel them on a wide range of cross-border insolvency issues, with particular emphasis on United States/Western Europe jurisdictions.

of hemp products such as seeds and oil (CBD), but sellers must be wary about the claims they attach to these products and may need to get creative with their advertising if they are trying to claim a health benefit.

Marijuana-derived CBD contains higher levels of THC than hemp CBD and falls under the umbrella of marijuana products that have been legalized for medical and recreational use by adults who are 21 or older. The CCC highlights the legality of adults 21+ to purchase recreational marijuana products from a licensed dispensary/retailer, as well as the increasing commonality of medical-marijuana cards being issued to qualifying patients.

A quick overview of the sale of CBD products in MA is that only marijuana-derived CBD can be sold to consumers in food-form and each purchaser must be 21 years of age or

Over the years he has cultivated extensive knowledge and skill in commercial and complex business litigation including veil piercings, corporate officer and director liability, successor liability, fraudulent conveyance and transfer litigation and constructive trust litigation. He also has experience counselling clients on distressed M&A transactions, corporate governance issues and complex business restructurings.

With offices in Boston, Fort Lauderdale, Fort Myers, London, New York, Stamford, Tampa and Austin, Curran Antonelli represents a wide variety of individuals, businesses, corporate entities, and governmental agencies in litigation and transactional matters throughout the United States and Western Europe. We have navigated a broad range of commercial litigation cases, including cross border insolvency, institutional creditors’ rights, bet the company litigation, and have earned a winning track record throughout the United States.

Our corporate group advises entrepreneurs, investment partnerships, private equity funds and venture capital firms on the legal, business and financial issues related to forming, financing, buying and selling, and investing in businesses. We counsel domestic and foreign firms in inward and outbound investments in a range of industries, including sports and entertainment, finance, communications, manufacturing, retail and consumer, and commercial real estate.

older, present a federally issued ID, and be purchasing from a licensed marijuana establishment. Hemp CBD is legal on a federal level, but it can only be sold in non-food and the sale of this type of CBD to consumers is not currently regulated.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

In the Commonwealth of Massachusetts marijuana use by adults 21 years of age or older is legal both recreationally and medically. To buy medical-grade marijuana products

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ Know the local laws for your municipality or town. These local laws impact where a marijuana facility can be placed, when it can do business, and what it can do. All registered marijuana establishments must comply with not only the laws of the Commonwealth of Massachusetts, but also all local ordinances, bylaws, and regulations.
- ✓ Have strong business and financial plans in place. Most financial institutions will not lend to a marijuana company due to the continuing Schedule I classification of marijuana, so it is important to make sure that the company has enough capital to pay for the pricy annual licensing fees and still have some breathing room.
- ✓ Create a network with other marijuana related companies in the state. Due to the criminality of marijuana it is still illegal to transport it across state borders. Because of this, it is important to know the other marijuana companies in the state that you may be doing business with.

patients with qualifying conditions must be approved by a physician, given a prescription for the use of medical marijuana, and an issued medical marijuana card must be presented before purchase. In order to promote safety, all purchasers of marijuana products from a retailer are required to show a government-issued ID and individuals can only have up to 1oz of marijuana on them when they are outside of the home. Additionally, using marijuana products in a public place is prohibited, as is driving while under the influence of marijuana products.

There are regulations for each step in the marijuana product sales process: commercial growers (cultivators), manufacturers, registered marijuana dispensaries or retail stores, and delivery. Each of these titles comes with their own licensing process that can quickly become costly – the annual licensing fee for a cultivator varies based on the size of the cultivator but can reach up to \$50,000, the annual licensing fee for a manufacturing license is \$10,000, the annual licensing fee for a dispensary license is \$10,000, and the annual delivery licensing fee is \$10,000. These fees help ensure that only well financed and legitimate marijuana businesses can sell to consumers.

It is important to note that municipalities and towns in Massachusetts can further regulate the use of marijuana products within their jurisdictions. Each jurisdiction can zone the adult use of marijuana and has the option to ban marijuana delivery within its borders. Additionally, towns can restrict the number of allowed marijuana establishments and govern the time, place, and manner of the operating marijuana establishments. Marijuana sales come with an excise tax, standard sales tax, and an optional local tax, making the marijuana business profitable for the state and more well regulated.

QUESTION ONE

What are the risks of CBD production and sales in your jurisdiction?

The production and sale of CBD and CBD products in Washington State is surprisingly fraught with potential risks. Those considering CBD production or sales in the state need to understand the legal landscape, how federal and state laws interact, and the gaps and areas of uncertainty that must be navigated. CBD producers and retailers must know, for example, which laws apply to which categories of CBD products, how pesticides are regulated and restricted, how to comply with applicable testing requirements, and how taxes differ for CBD products regulated under the state's recreational cannabis framework versus those which are not. Entering the market without this information could expose a CBD business to enforcement actions and, potentially, the need to make costly infrastructure changes. Moreover, the presence of significant gaps in the regulation of CBD in Washington means there is substantial uncertainty from production to end-user experience. Indeed, it may not be clear what is actually in CBD products sold at retail, what packaging and marketing restrictions apply, and what product liability issues CBD businesses could face.

CBD producers and retailers should also be attuned to the structure and dynamics of the market. For example, because industrial CBD production is allowed, the competitive landscape involves unique production scale issues that impact smaller growers and producers in ways that are not present in the THC space.

“Topicals, lotions, and tinctures which contain less than 0.3% THC can be purchased in brick-and-mortar stores or online.”

QUESTION TWO

What are the different types of CBD products and how are they defined?

Many different types of CBD products are available in Washington State – from topicals, lotions, and tinctures, to edibles, vape pens and cartridges. Topicals, lotions, and tinctures which contain less than 0.3% THC can be purchased in brick-and-mortar stores or online. These types of products are described as “cannabis health and beauty aids,” defined as “a product containing parts of the cannabis plant and which: (a) Is intended for use only as a topical application to provide therapeutic benefit or to enhance appearance; (b) Contains a THC concentration of not more than 0.3 percent; (c) Does not cross the blood-brain barrier; and (d) Is not intended for ingestions by humans or animals.” RCW 69.50.575. Topicals, lotions, and tinctures can contain a higher concentration of THC. But if they do, they must be processed and sold in accordance with Washington’s recreational cannabis statutes and regulations.

CBD edibles, beverages, and vape products are not similarly available. These types of products can only be sold by state licensed cannabis retailers in compliance with statutes and regulations governing recreational cannabis in the state –



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Duncan Manville is an experienced, pragmatic and creative counselor and litigator. He helps private and public clients avoid disputes, and, when they can't be avoided, resolve them through negotiation, mediation, arbitration and litigation.

Duncan has successfully represented cannabis business and other clients in matters ranging from small disputes to multi-million-dollar bet-the-company litigation. He handles breach-of-contract, employment, intellectual property, real estate and securities cases, lawsuits involving a variety of tort claims, and other commercial litigation matters.

Brandi Balanda has wide-ranging experience successfully litigating large, complex commercial cases and engaging in creative problem solving to guide institutional and individual clients through dispute resolution – whether by negotiation or by

regardless of the amount of THC they contain. The federal Food and Drug Administration and the Washington State Department of Agriculture, which regulate CBD production and sale in the state following the 2018 Farm Bill and subsequent Washington State legislation, do not permit CBD to be added to food and beverages or sold as dietary supplements. So, while you can find a CBD infused cream at your local health or beauty store if it contains less than 0.3% THC, you must go to a state licensed cannabis retailer to find a beverage or edible containing any amount of CBD. Similarly, CBD vapor products are only available through Washington's recreational cannabis regulatory framework. Washington State does not otherwise permit their sale or distribution.

litigating claims and defenses in court and in arbitrations.

In the cannabis space, Brandi has represented retailers in a variety of matters, including disputes involving real estate, advertising, and other issues faced by state-licensed cannabis businesses. She recently obtained key victories for a major industry player regarding its intellectual property, including injunctive relief against trade secret theft and trademark infringement, and successfully defended her client against employment and defamation claims.

We're litigators and trial counsel. We know that cases are won and lost on their "story": who is right and who is wrong in the eyes of the judge and jury. Our expertise is in developing and telling that story by drawing out the key facts, players, and themes, defining the legal framework in which they operate, and weaving them into a compelling narrative

Our skill as litigators informs every step along the way. Understanding the facts requires not only an eye for detail but a strategy that identifies the right detail, combined with the tenacity to obtain and marshal complex facts and develop a record that completes the picture.

We believe in the power of what can be achieved in the courtroom, but one size does not fit all. Our successes demonstrate the ability to develop winning strategies that meet the unique needs of each case. We know when a major investment of people and time will yield results and when it just means a big bill, and we're committed to identifying cost-effective solutions to our clients' problems. If there is a way to resolve a dispute successfully short of trial, we find it.

QUESTION THREE

What is the current legal status in your jurisdiction? Is there an adequate legal framework?

Under the federal Controlled Substances Act of 1970 (21 U.S.C. § 801 et seq.), cannabis is a Schedule I substance the possession and use of which is unlawful.

Under Washington law, however, cannabis is broadly legal for medical use, and also for recreational use by adults. In 1998, the Medical Use of Cannabis Act (codified at RCW ch. 69.51A)

TOP TIPS

On ensuring commercial success in your jurisdiction

- ✓ **Engage Experienced Local Counsel.** The existence of a decade-old legal recreational cannabis market, and the more recent passage of federal and state legislation to legalize hemp production, suggest that doing business in the cannabis space in Washington is straightforward and easy to jump into. For businesses, the industry is highly regulated and rife with potential operational and legal landmines. Given the patchwork of laws and the evolving landscape, engaging experienced local counsel is critical for the creation and maintenance of a profitable cannabis business.
- ✓ **Be Strategic Instead of Reactive.** Although the industry is highly regulated, it also provides unique opportunities for innovation and growth.
- ✓ **Gain Consumer Confidence with Trusted Products.** Many cannabis players and their products have come and gone since the passage of I-502 in 2012. Success and sustainability require building brand and product loyalty through quality and consistency.

made it legal for patients with qualifying medical conditions to use cannabis and to possess and grow it in small quantities. In 2012, Initiative 502 (codified at RCW chs. 69.50, 46.20, 46.61 and 46.04) legalized the recreational use of cannabis by adults, subject to purchase limits and other restrictions.

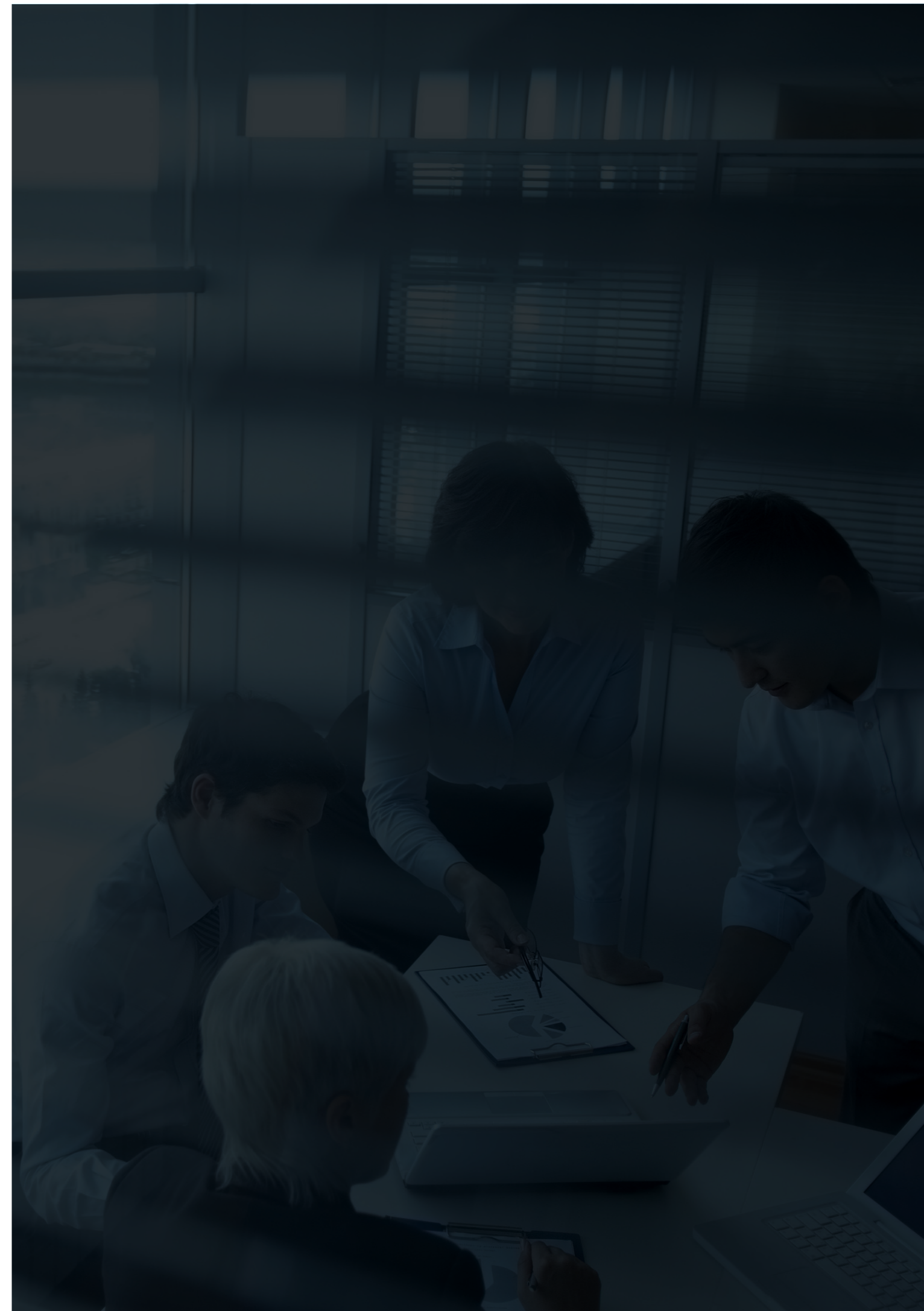
There is, of course, considerable tension between federal laws making the production, sale, possession and use of cannabis illegal, and state laws and county and municipal ordinances legalizing and regulating these activities.

To date, the federal government has not cracked down on cannabis businesses or consumers acting in accordance with state law. But federal enforcement of the Controlled Substances Act remains a possibility. Indeed, in January 2018, then-U.S. Attorney General Jeff Sessions issued a memorandum rescinding a 2013 policy statement known as the “Cole Memo,” which had given cannabis businesses some breathing room in jurisdictions where cannabis was legal under state law. The rescission of the Cole Memo signaled a return to a more hard-line approach to the enforcement of federal cannabis laws, although this has not translated to a material change in federal practice.

Of greater day-to-day significance to cannabis producers and retailers is the fact that many banks will not do business directly with them, either out of concern over possible federal government sanctions, or because of the additional regulatory burdens attendant to servicing the cannabis industry. Moreover, although some cannabis retailers claim to accept credit cards, the major credit card companies do not allow their cards to be used for cannabis purchases. As a result, cannabis remains basically a cash business in Washington, even for producers and retailers who are operating legally under state law.

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