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The globalization of cannabis – 2020 and where do we grow from here?

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Eric Foster has been advising clients in the cannabis industry since its inception and is the leader of Dentons' Canadian cannabis practice. Eric is recognized as one of Canada's leading cannabis lawyers and is one of only 3 lawyers in Canada to receive a Band 1 Ranking for Cannabis Law by each of Chambers & Partners and The Legal 500 Canada Guide. In November 2020, Eric was named a winner of the *Lexpert Rising Stars Awards: Leading Lawyers Under 40* for 2020.

Eric's practice focuses on cannabis law, corporate finance, mergers and acquisitions, regulatory compliance and corporate governance. Eric routinely acts as lead counsel to Canadian, U.S. and international cannabis companies and assists licensed producers, retailers and other cannabis industry stakeholders with commercial agreements including cannabis royalty, offtake, supply and licensing arrangements. He also regularly advises issuers, securities dealers and institutional investors on a wide range of financing transactions, including IPOs, secondary offerings and other forms of equity and debt financing.

Eric is a sought after speaker in the cannabis industry and has made appearances in multiple media outlets including Bloomberg, The Globe & Mail, The Financial Post, CTV News and Leafly.

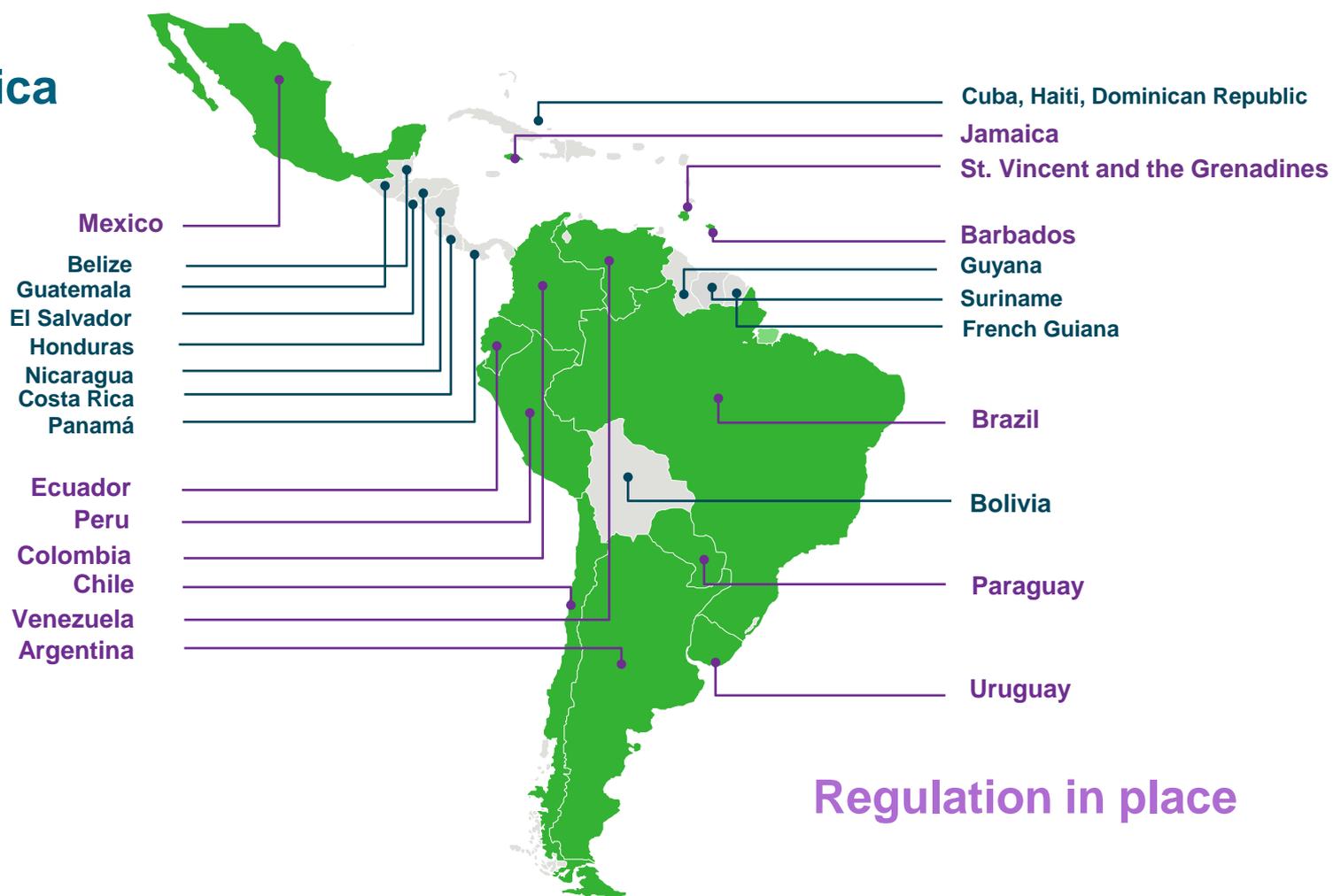


Latin America and the Caribbean

Overview

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Latin America and the Caribbean Overview



Regulation in place

Latin America and the Caribbean overview

Taxes – specific for cannabis

Brazil:
(CBD and THC)
2% of Import Tax
11.75% of the contribution
(PIS and COFINS) at the
federal level.



Colombia:
Sale of Final
Products containing
psychoactive or
non-psychoactive
cannabis.
16% of final
products' value.



Latin America and the Caribbean overview

Advantages

Conditions

- Climate
- Altitude
- No seasons
- Low labor and production costs

Background

- Know-how
- Varieties
- Strains and seeds
- Authorities are strict with the industry

Quotas

- Highest quotas from the INCB to Uruguay, Colombia, Jamaica

Latin America and the Caribbean overview

Challenges

Banking

- Stringent requirements to open bank accounts
- US banks cannot serve as intermediaries

Licensing

- Regulation is insufficient or contains loopholes or different interpretations
- Delays

Thank you



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Catalina is a partner in the Firm's Life Sciences and Health Care group, with a focus in the cannabis practice. She has more than 15 years of experience and has been with the Firm since 2009. Her work in the LSHC group began in 2017, when the regulation for medicinal and scientific use of cannabis in Colombia was issued.

Her transactional work includes cross-border M&A and listings in the Toronto Stock Exchange of companies with key assets in Colombia. She has advised local and foreign cannabis companies in their affairs in Colombia, including incorporation, foreign investment, licensing and regulatory issues, as well as commercial agreements and real estate acquisitions.

Catalina has an LL.M. in corporate law from New York University (USA) and is admitted to practice in the state of New York.

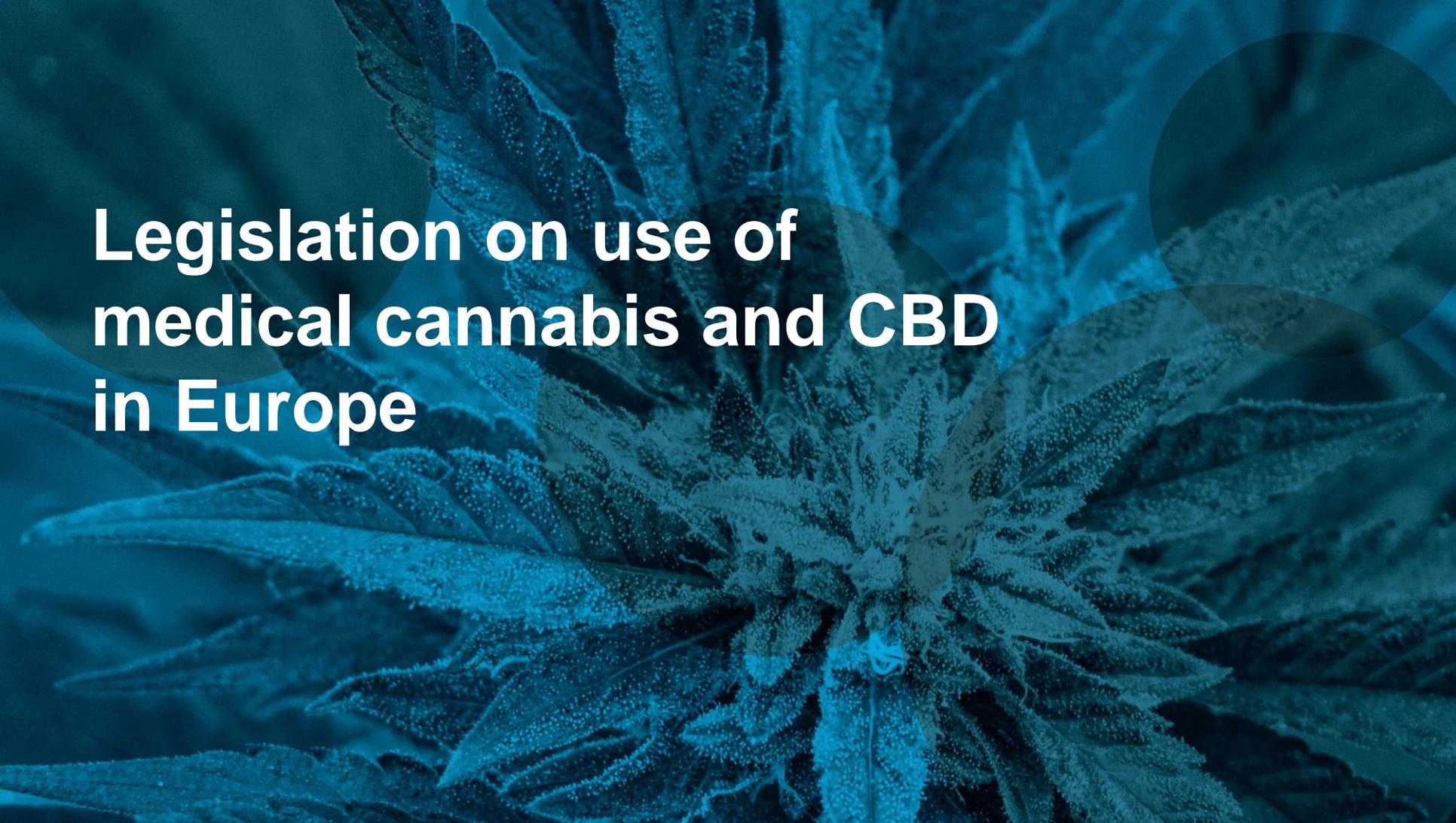
The globalization of cannabis – 2020 and where do we grow from here?

European Overview

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Overview

- (1) Legislation on the use of medical cannabis and CBD in Europe
- (2) The medical cannabis industry in Germany
- (3) The development in other EU Member States



Legislation on use of medical cannabis and CBD in Europe

Legislation on use of medical cannabis in Europe

- Currently, there is **no harmonized legal framework** on the use and distribution of medical cannabis as a narcotic in the EU; it is thus mostly regulated by the national law of each Member State.
- The regulatory environment regarding medicinal cannabis within the EU is very **heterogeneous**; the only harmonized standards within the EU are:
 - The **1961 Single Convention on Narcotic Drugs** (Art. 23 and 28); and
 - The **pharmaceutical quality standards** of such products (i. e. Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP)); the **overlap between GACP and GMP**, particularly for the **drying step**, still creates some confusion in the cannabis industry.

Activity	Good Agricultural and Collection Practice (GACP) ⁴	Part II of the GMP Guide [†]	Part I of the GMP Guide [†]
Cultivation, collection and harvesting of plants, algae, fungi and lichens, and collection of exudates			
Cutting, and drying of plants, algae, fungi, lichens and exudates *			
Expression from plants and distillation **			
Comminution, processing of exudates, extraction from plants, fractionation, purification, concentration or fermentation of herbal substances			
Further processing into a dosage form including packaging as a medicinal product			

Legislation on use of CBD in Europe

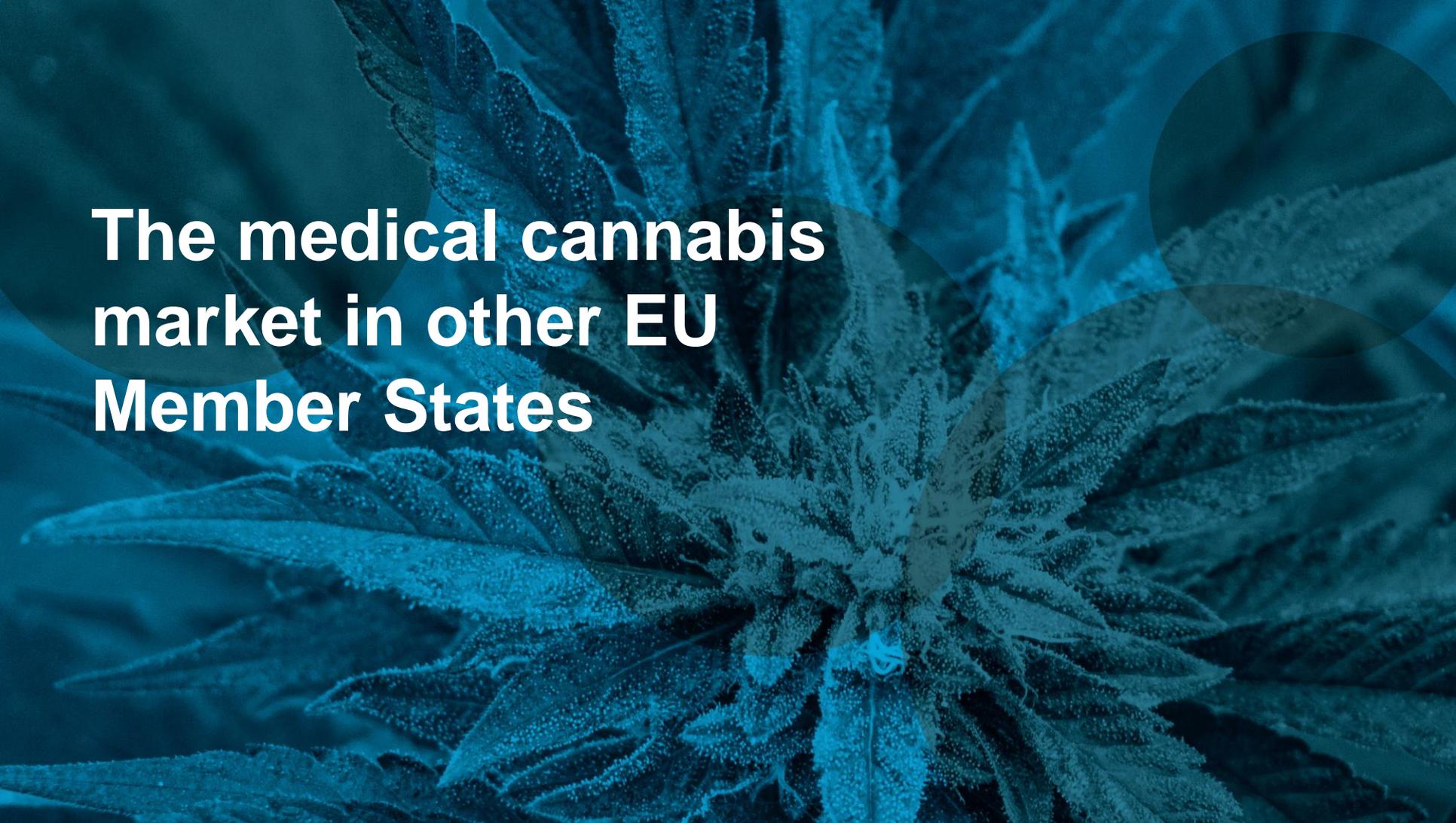
- CBD as **Novel Food** requires a **European Novel Food Authorization**
 - There are currently **55 pending applications** to the EU Commission for authorisation of the CBD-containing product as a novel food → all not yet ready for authorisation; many do not even qualify as food; scientific data is missing.
 - The European Commission recently announced its preliminary view that CBD extracted from the flowering tops of the Cannabis sativa L. plant should be considered a **narcotic** under a 1961 Single Convention on Narcotic Drugs; applications for novel food authorizations have been **postponed**.
 - The 53 member states of the **CND** (Commission on Narcotic Drugs of the United Nations) vote on whether to revise how cannabis and related substances are scheduled in the Single Convention is scheduled for **December 2020**.
 - In December 2019, the European Commission issued a proposal for a united position on the WHO scheduling recommendations; The European Commission does **not support**:
 - Recommendation 5.4: Removing extracts and tinctures of cannabis from Schedule I of the 1961 convention.
 - Recommendation 5.5: Adding a footnote saying that “preparations containing predominantly cannabidiol and not more than 0.2% of delta-9 tetrahydrocannabinol are not under international control.”
 - However on **19 November 2020**, the **European Court of Justice** decided: **CBD is not a narcotic**.



The medical cannabis industry in Germany

The medical cannabis industry in Germany

- Germany is **Europe's largest medical cannabis market**, the **third largest cannabis market behind the US and Canada** and is still growing.
- Until the beginning of domestic cultivation, Germany remains completely dependent on **imports**.
- The quantities estimated by the **INCB** for the requirements of cannabis in Germany (for medical and scientific purposes; contains extracts, flowers and other forms) were:
 - about **10.7 tonnes in 2018**
 - about **20.8 tonnes in 2019**
 - About **31.5 tonnes in 2020**
- The BfArM's tender on the **cultivation** of medical cannabis in Germany, which was successfully completed in May 2019, covers a total of **10,400 kg over a period of four years** with 2,600 kg each; this quantity can increase up to 150 % of the annual planned requirement; according to the German government, there will be no cannabis from German cultivation in 2020; cultivation is **delayed** (Q1 2021).



The medical cannabis market in other EU Member States

The development in other EU Member States

- **Greece:** Companies can obtain **licenses** to install and operate medical cannabis processing and production plants for the sole purpose of either **supplying the state monopoly** on the provision of cannabis for medical purposes, or for the **export** of these products.
- **Ireland:** In June 2019, the Minister for Health signed legislation to allow for the operation of the Medical Cannabis Access Programme on a **pilot basis** for **five years**.
- **Luxembourg:** Luxembourg has announced that it will enable **full cannabis reform by 2022**. In August 2019 Luxembourg's health minister announced plans to become the first European country to legalize cannabis production and consumption.
- **France:** France continues to adopt a **conservative stance** on medicinal cannabis, and it is not yet legal, though Sativex is available on prescription; however, on October 7, the French released news of a **medical trial** finally being instituted in the country no later than **March 31, 2021**, and to run for a period of **two years**. The French government is officially looking for suppliers for its medical cannabis trial.
- **Denmark:** On 1 January 2018, the Danish Medicines Agency established the **medicinal cannabis program**. This **four-year pilot scheme** granted 12 companies permits for growing, cultivating and distributing medicinal cannabis in the country. They are now free to distribute their products to approved suppliers. The country anticipates becoming one of the largest producers of medicinal cannabis in Europe.

The development in other EU Member States

- **UK:** On 1 November 2018, the prescription of medicinal cannabis was codified into law by an amendment to Schedule 2 of the 2001 Misuse of Drugs Regulations. This allows clinicians to prescribe cannabis as an unlicensed medicine; The UK company, GW Pharmaceuticals, is the **largest exporter of legal medical cannabis in the world**, cultivating medical cannabis for production of cannabis-based medicines (e.g. Epidiolex & Sativex).
- **Switzerland:** The Swiss Parliament has passed a motion calling for a change in the country's cannabis law. It allows to export cannabis and authorizes regular doctors to prescribe cannabis directly. It is expected that the new law will come into effect sometime in **mid-2021**.
- **Spain:** Spain's laws are liberal when it comes to cannabis use; **private use is decriminalized** and there are several 'cannabis social clubs' across the country; although Spain is progressive in its decriminalization of personal cannabis use, it is lagging behind in terms of its medicinal cannabis laws. These laws do not differentiate between recreational and medicinal cannabis use. This means that patients cannot obtain a prescription for cannabis products that contain 0.2% THC or over. Currently, there are **only limited medicinal cannabis products** available on medical prescription. Sativex, Epidiolex, Nabilone and Dronabinol can be prescribed. There are currently **only ten companies** in Spain who have the right to cultivate the plant.

Thank you



Peter Homberg

Partner

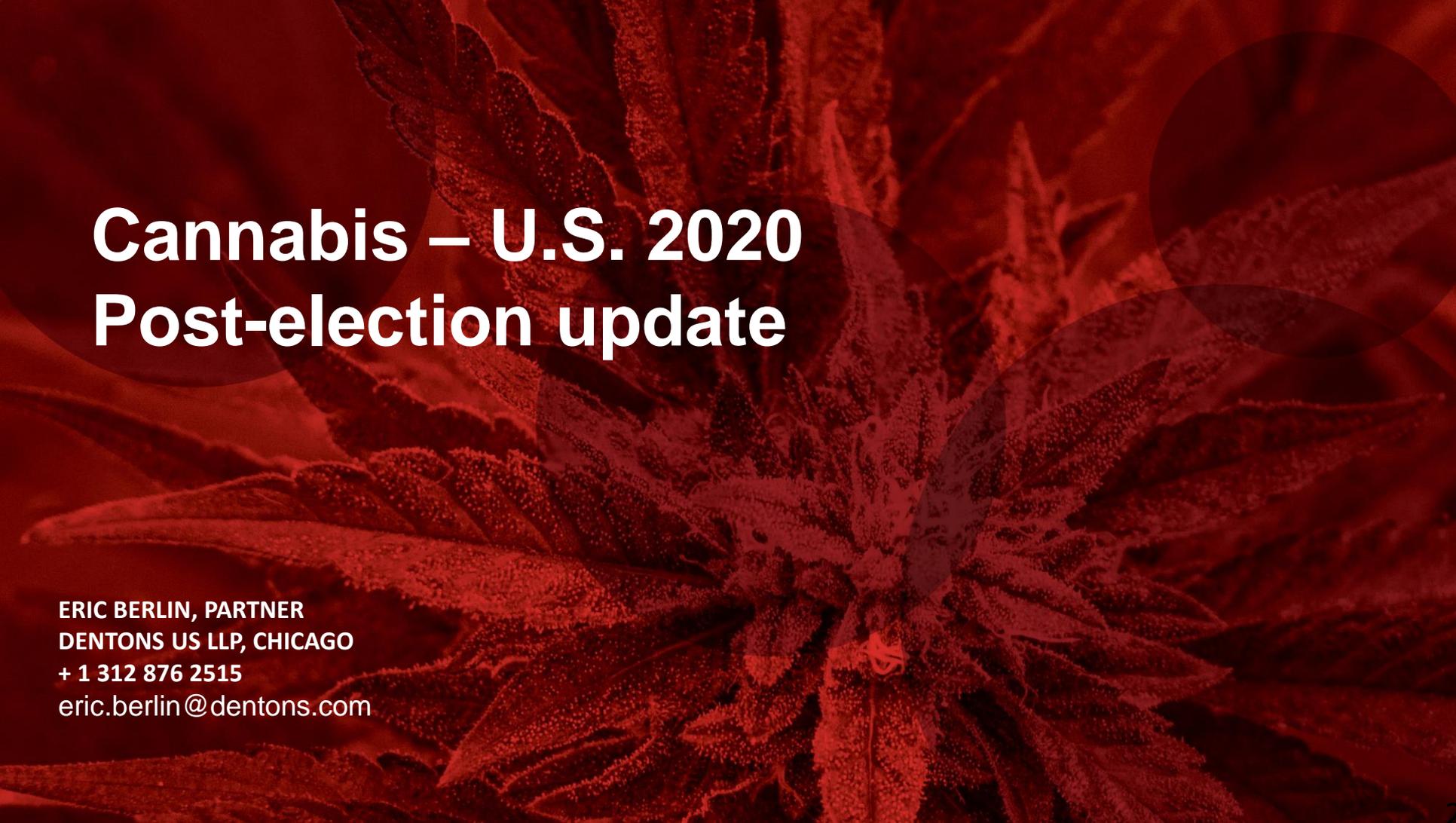
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Peter Homberg is a partner in the Dentons Berlin office. He specializes in IP, corporate law and M&A transactions in the life sciences and high-tech sector as well as in R&D and cooperation agreements, cross-border IP licensing and IP strategies. Peter advises inter alia companies in the pharmaceutical, diagnostics, biotechnology and medical device industry – from startups to large publicly listed companies. Furthermore, he has broad transactional experience in Southeast Asia.

Peter is member of the Licensing Executive Society (LES), the German Association for Intellectual Property and Copyright (GRUR), the German Institution for Arbitration (DIS) as well as the Pharma-Lizenz-Club Deutschland e.V. He regularly holds lectures at seminars and conferences and is also author of numerous professional articles and other publications regarding corporate or IP law in the field of life sciences.



Cannabis – U.S. 2020 Post-election update

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Eric Berlin

- Leads Dentons US Cannabis Group
- Law360 2020 MVP for Cannabis
- Helped draft/pass Illinois & Ohio medcanna laws
- 100% time spent on clients in or impacted by legal cannabis or hemp/CBD industries



What Is Cannabis in the U.S.?

Hemp (<0.301% THC)

“Marijuana” (>0.3% THC)



- + Extracts from glands on flowers & leaves containing cannabinoids, terpenes and flavonoids

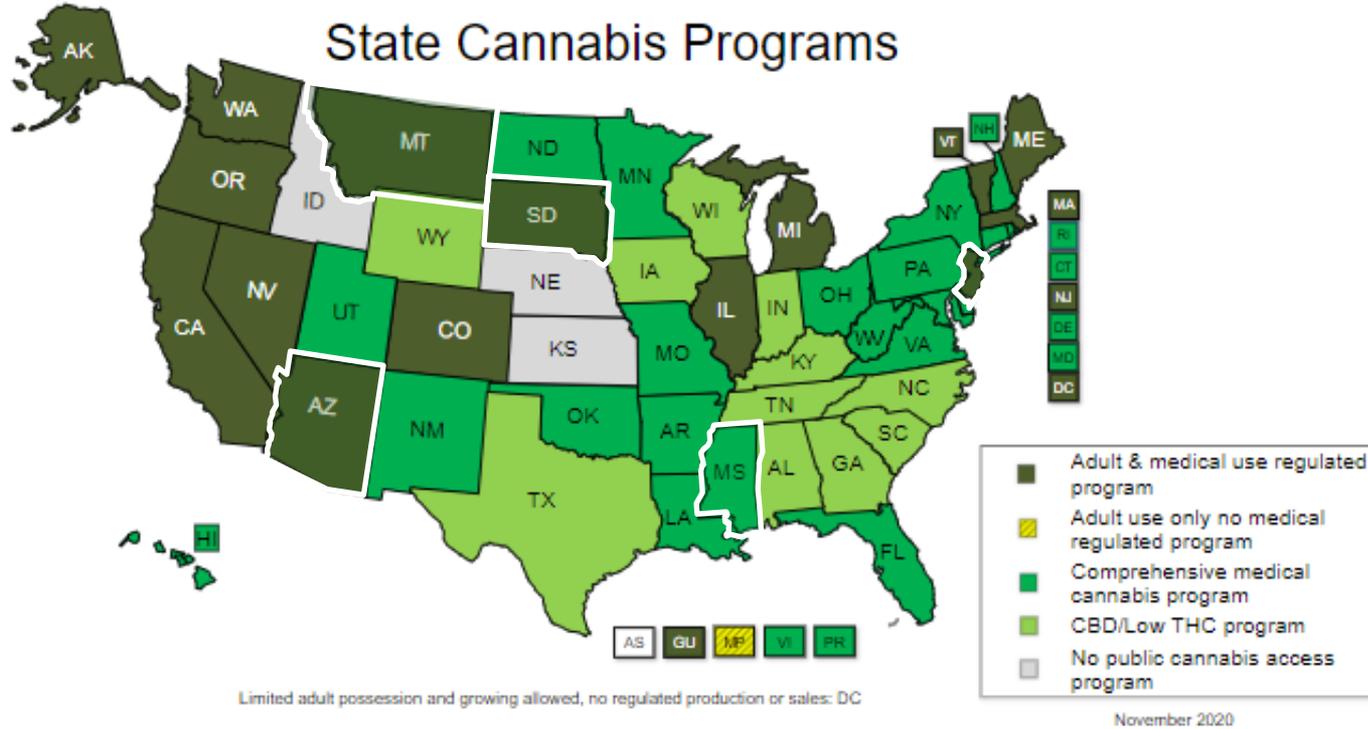
Hemp in the U.S.

- **2018 Farm Bill** - Hemp no longer CS
- **FDA** - Warns CBD (or THC!) in ingestible or in any product with health claims is illegal
- **USDA** - Onerous testing rules
- **DEA** - Interim Final Rule
- **State Laws** - Vary

2020 Landslide for State Ballot Initiatives

- **Arizona** - Adult use, passed with 60% of vote
- **New Jersey** - Adult use, with 67%
- **Montana** - Adult, 57-58%
- **South Dakota** - Medical, 69% & Adult, 53%
- **Mississippi** - Medical, 74%

Current U.S. State Laws - Nov. 2020



Implications of U.S. Federal Illegality

- No **import/export** of THC products to/from U.S.
- Limited **banking** & impact on credit cards
- Limited **IP** protection
- No federal **bankruptcy** protection in U.S.
- Limited **access to capital**



President-Elect Biden's Position

- **Decriminalization**
 - Not full legalization
 - Expungement for past convictions
- **Increased cannabis research**
- **Schedule II**
 - Move cannabis from Schedule I to II under CSA

U.S. Federal Cannabis Reform

- **SAFE Banking Act**

- Would permit banks to work with licensed cannabis operators

- **MORE Act**

- Removes cannabis from list of Controlled Substances
- Social equity & reparative justice

- **STATES Act**

- Respects State laws that legalize cannabis

- **Full Legalization**

Thank you



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Eric is one of the nation's leading cannabis law authorities, advocating full-time for clients in, or impacted by, the state-legal cannabis industries and tensions with federal law. With more than two decades of courtroom and jury trial experience in high-stakes matters, Eric is ideally suited to counsel companies in this fast-growing industry on how best to achieve their business objectives while avoiding the legal risks of operating in a rapidly evolving regulatory environment brimming with tension between federal and state law. Current clients include large publicly traded companies selling products or services into the cannabis industry, companies involved in financing the industry, vaporizer manufacturers, health care institutions, testing labs, cultivators, processors, and a company operating dispensaries in several states. Eric is a member of the Health Care group and works with colleagues in other practices to provide counseling and compliance advice on numerous other laws applicable to these evolving businesses, from laws governing the employment relationship to laws protecting intellectual property rights. Eric also counsels clients on risk management and litigation avoidance, and provides legal assistance in all types of commercial and corporate transactions.

Eric has also provided government advocacy services at the state level. He worked with members of the Illinois and Ohio legislatures to draft and get passed bills creating medical marijuana dispensaries. He has represented large, publicly traded companies that sell products or services to the cannabis industry, companies involved in financing the industry, vaporizer manufacturers, testing labs, cultivators and processors, and dispensary operators.