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# Medical Cannabis & Cannabinoid Regulation

**Switzerland**
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# SWITZERLAND

## Law and Practice

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## 1. LEGAL/REGULATORY FRAMEWORK

### 1.1 Source of Regulations

In Switzerland, products containing hemp, or *Cannabis Sativa L.* (cannabis), are regulated by a set of laws and regulations that are intertwined, complex and create a level of legal uncertainty that lawmakers have realised needs to be addressed. The main tenets surrounding cannabis are regulated in the narcotics, therapeutic products, health insurance, foodstuff, chemical, cosmetic, utility articles, tobacco substitutes as well as plant varieties and seeds laws and regulations, among others.

To facilitate matters, this guide will provide an overview of only the most important aspects of cannabis laws and regulations, and draw a distinction between cannabis products:

- containing a tetrahydrocannabinol (THC) content of above 1%, which are considered prohibited narcotics under the Federal Act on Narcotics and Psychotropic Substances (Narcotics Act, NarcA); and
- containing a THC content below 1%, which have been popularised and aggregated (in somewhat untechnical jargon) as "CBD products" – which means products containing cannabidiol – which are not subject to the NarcA and are more freely marketable.

THC and CBD have garnered notoriety as the most prominent cannabinoids over the last years, but research has shown that over 140 cannabinoids (naturally occurring compounds found in the cannabis plant) can be identified.

#### Cannabis Products with a THC Content Above 1%

##### *Narcotics Act, NarcA*

The use of narcotics is primarily regulated by the NarcA. The implementation of the NarcA is governed by three ordinances on the control of narcotics (BetmKV), the addiction to narcotics (BetmSV) and the register of narcotics, psychotropic substances, precursors and auxiliary chemicals (BetmVV-EDI).

The BetmKV governs the activities of the Swiss Agency for Therapeutic Products (Swissmedic) in the area of granting authorisations for the legally permitted handling of controlled substances and the associated controls, and is of importance for the industrial use of these substances. The BetmSV regulates the measures for prevention, therapy and harm reduction as well as the exemptions for the restricted medical use of cannabis-containing medical products and the corresponding controls. Lastly, the BetmVV-EDI lists all controlled narcotics and psychotropic substances and determines to which control measures they are subjected.

Cannabis is classified as a prohibited narcotic if its THC content exceeds 1%. An amendment to the NarcA in force since 1 July 2011 provides for a restricted decriminalisation of the preparation of a negligible quantity of cannabis for one's own consumption (10 g). Cannabis products with a THC content lower than 1%, on the other hand, can be legally produced and marketed. This holds true for all cannabis products except for cannabis resin. Cannabis resin is separately listed in the BetmVV-EDI and is considered a controlled narcotic, independent of its THC content. This classification of cannabis resin as a narcotic drug, which was confirmed by the Swiss Federal Tribunal in 2019, is considered rather unfortunate by the local cannabis industry as it limits the commercial exploitation of the most cannabinoid-dense part of the cannabis plant, drives a wedge of unequal treatment between cannabis extracts, which are legal if their total THC content remains below 1%, and cannabis resin, and creates a whole range of other legal issues (eg, in cosmetics regulation).

Pursuant to the NarcA, the Federal Office of Public Health (FOPH) may issue exceptional licences for cultivating, importing, producing and placing on the market narcotics containing an effective concentration of cannabinoids, where this is not prohibited by an international agreement and these narcotics are needed for scientific research, the development of medical products or for restricted medical use. The prescription for medical purposes of unauthorised cannabis-based medical products which contain a THC level of above 1% is permitted under certain circumstances. Such an exemption permit from the FOPH is required:

- to develop medical products with prohibited narcotics;
- to use prohibited narcotics for limited medical purposes; and
- to use an authorised medical product with prohibited narcotics for any purpose other than the approved indication.

An exceptional licence for restricted medical use is issued to the attending physician. The physician then goes on to prescribe the medical cannabis product (in the form of oils and tinctures for ingestion). Based on this prescription, the corresponding medical product may be dispensed to the patient within the framework of the Therapeutic Products Law. The granting of a licence for the restricted medical use of prohibited narcotics also requires a prior written declaration by the patient stating that he or she consents to the use. An exceptional licence for restricted medical use may only be granted if the following conditions are cumulatively fulfilled:

- the patient suffers from an incurable disease;
- the suffering can be alleviated by taking the prohibited narcotic;
- the existing treatment options have been exhausted or there are no alternative treatment options; and
- the administration of the prohibited narcotic enables the patient to live more independently (eg, in case inpatient treatment can be avoided).

Applying for a special permit at the FOPH is therefore quite cumbersome, and a revision to the NarcA, which was adopted on 19 March 2021, will provide long-sought relief. See the adjacent **Trends & Developments** article for further details.

### Therapeutic Products Law

#### *Legal basis*

The regulations on the use of medical products and medical devices are mainly set forth in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), the Ordinance on Pharmaceutical Products (VAM), the Ordinance on Advertising of Pharmaceutical Products (AWV) and the Products Licensing Ordinance (MPLO). These laws and regulations apply to therapeutic products according to the TPA, which include medical cannabis products.

#### *Authorisation*

Ready-to-use medical products may be placed on the market only if authorised by Swissmedic. The application for obtaining a market authorisation for medical cannabis products must include, for example, detailed documentation on the results of physical, chemical, galenic and biological or microbiological tests, as well as the results of pharmacological and toxicological tests and clinical trials. The applicant must prove that the medical products are of high quality, safe and effective and that the medical product in question does not pose a risk to the safety of consumers.

Only one ready-to-use medical product with a THC content above 1%, Sativex®, is fully approved in Switzerland. Sativex can be prescribed without special permit only for spastic

convulsions in multiple sclerosis patients – in other words, its application is very limited in scope.

The manufacture of medical products and pharmaceutical excipients (eg, colourings, preservatives) whose manufacture requires a licence must conform to the recognised rules of good manufacturing practice (GMP). The Medicinal Products Licensing Ordinance (MPLO) refers to the GMP guidelines of the European Union (Annex 1). Thus, in Switzerland the GMP guidelines of the European Union are applicable.

The GMP guidelines provide the minimum requirements that a manufacturer of medical products must meet to assure that their products are consistently of sufficiently high quality for their intended use. This includes risk management, documentation, continuing improvement processes as well as internal and external audit requirements. Each manufacturer must determine and document in writing how it complies with and implements the GMP guidelines. An audit must verify whether all the required boxes of the GMP standard were ticked and thus that the products meet the safety and quality standards.

Swiss-domiciled companies with a valid establishment licence for the manufacture of medical products may apply to Swissmedic to obtain a GMP certificate through its eGov GMP-GDP online portal.

### *Exemption from authorisation*

The Therapeutic Products Act also provides for the market placement of medicinal products that are exempt from authorisation. These include medical cannabis products manufactured as an extemporaneous preparation ("magistral formula") – ie, medicinal products prepared according to a doctor's prescription by a public pharmacy or a hospital pharmacy for a given person or group of persons.

The conditions for the use of medicinal products that are exempt from authorisation are restrictive. Such use is mainly considered in order to ensure the supply if no authorised drug is available for this purpose. Medical cannabis products produced as a formula magistralis, which are produced by a pharmacy based on a medical prescription, require an exceptional authorisation from the FOPH under the NarcA. An exceptional authorisation is also required for an approved drug (ie, Sativex®) that is dispensed for an indication other than the one for which it has been approved.

The reason for this exemption from authorisation is, according to the legislator, that the training of the physician and the cantonal supervision of the professional licences guarantee that the physician issues the prescriptions correctly and the pharmacist prepares the prescriptions according to the law.

The provisions of the TPA apply to narcotics used as therapeutic products even if they are placed on the market with an exceptional authorisation under the NarcA. The provisions of the NarcA are applicable to these narcotics insofar as the TPA does not provide any regulation or provides a less far-reaching regulation than the NarcA. In other words, narcotics used as medicinal products that are exempt from an exceptional authorisation by Swissmedic also must comply with the minimum standards of the TPA.

### *Health Insurance Law*

The reimbursement of costs for medicinal products by the compulsory health insurance (OKP) generally requires that the medicinal product is included in the so-called list of specialties (SL) of the FOPH. To be included in that list, the medici-

nal product requires both a licence from Swissmedic and proof of its efficacy, usefulness and cost-effectiveness.

In Switzerland, it is considered that there is limited evidence for the efficacy of cannabis inter alia in the treatment of chronic pain, nausea in chemotherapy and spasms in multiple sclerosis. Accordingly, no medicinal product, not even Sativex®, is on the FOPH's list of specialties for reimbursement by the compulsory health insurance.

Only in cases of hardship, and upon request for a cost approval by a physician, is reimbursement by the OKP of a medicinal product not listed in the SL possible. It is considered a case of hardship if the use of the product is expected to provide a major therapeutic benefit against a disease that may be fatal for the insured person or result in severe and chronic health impairments, and no other effective and approved treatment method is available due to a lack of therapeutic alternatives.

It remains to be seen whether an amendment to the NarcA, which was adopted by the Swiss Parliament on 19 March 2021, will provide relief in terms of reimbursement by the OKP. Unfortunately, the adopted amendment does not envisage an adjustment to the reimbursement requirements. However, a so-called Health Technology Assessment (HTA) report is being prepared on behalf of the FOPH to clarify the scientific evidence regarding the efficacy and cost-effectiveness of medical cannabis products and to differentiate between the various patient groups. The HTA will form the basis for the reimbursement decision on medical cannabis products that do not require a marketing authorisation. It may be published later in 2021.

### Cannabis Products with a THC Content Below 1%

Cannabis products containing a THC content of below 1% are not captured by the scope of the NarcA. Of all the (known) cannabinoids in the cannabis plant, CBD stands out as the most prominently marketed cannabinoid in the cannabis market. On 21 April 2021, Swissmedic, the FOPH, the Federal Food Safety and Veterinary Office (FSVO) and the Federal Office for Agriculture (FOAG) jointly released an updated version of an "Overview and implementation guide" regarding "Products containing cannabidiol (CBD)" (the "Implementation Guide"), the main elements of which are set out below.

CBD products can only be marketed legally if they comply with the Swiss legislation that is applicable to their respective classification. The range of CBD-containing products is extensive and includes, among others, raw materials such as cannabis buds or flowers with a high CBD-content, extracts in the form of oils or pastes, ready-to-use products such as capsules, food supplements, liquids for e-cigarettes, tobacco substitutes, scented oils, chewing gums and ointments, some of which are offered as personal care products.

In order to determine the applicable legislation, the product must be assigned to the corresponding product category based on the relevant factors such as composition, intended use, dosage, etc.

As an initial step, it must be determined whether the CBD product is a raw material or ready-to-use product. CBD products considered as raw materials are governed by the Chemicals Act and the Chemicals Ordinance. If no intended use can be determined for a cannabis-based raw material, it should be placed on the market in accordance with the legislation governing chemicals. Lastly, the Federal Act on Product

Safety (PrSG) acts as a fallback catch-all legislation for products for which there is no other specific applicable law.

### *CBD offered as chemicals*

CBD-containing products may be marketed legally as scented oils. Manufacturers must classify, package and label the product in accordance with the provisions of the Chemicals Ordinance (ChemO) after having assessed that substances or preparations they intend to place in the market do not endanger human life, health or the environment.

However, if the presentation of the products indicates, or suggests, other uses that are covered by other legal provisions, their marketability must be assessed according to these provisions. This may be the case, for example, if a "scented oil" is sold in a cartridge for e-cigarettes, in which case foodstuffs/utility articles legislation applies for the assessment of marketability. The same would apply if, for example, cannabis oils containing full spectrum hemp extracts would be labelled as having a specific nutritional value, or is sold under the banner of a therapeutic product.

The authorities are applying a holistic approach in their assessment of product classification, which also includes a detailed analysis of how CBD-containing products are marketed through company websites and other sales channels.

### *CBD sold as medicinal products*

Ready-to-use CBD-containing products with a medical-intended use are regarded as medicinal products under the TPA, which require authorisation by Swissmedic to be placed on the market. Companies that manufacture, distribute or dispense medicinal products containing CBD always require a corresponding authorisation from Swissmedic or the respective canton.

Epidiolex®, a ready-to-use CBD monopreparation prescribed for the adjuvant treatment of two rare forms of epilepsy, was approved by the United States Federal Drug Administration (FDA) on 28 June 2018. This was the first time a ready-to-use CBD medicinal product has been approved anywhere in the world. Recently, on 10 February 2021, the same preparation was approved in Switzerland under the name of Epidyolex®.

Pharmacies can also prepare and dispense CBD containing medicinal products as extemporaneous preparations – ie, as a magistral formula, based on a prescription of a specialised physician – in Lennox-Gastaut syndrome and Dravet syndrome or other treatment-resistant forms of epilepsy. The medicinal product must be prepared with CBD that has been produced in compliance with GMP to a quality standard that as a minimum satisfies the requirements of monograph C-052 Cannabidiol of the current German Drug Codex DAC/NRF and the preparation itself at the pharmacy level must comply with the GMP requirements of the current *Pharmacopoea Helvetica* (Ph. Helv.).

### *CBD sold as cosmetics*

According to the Ordinance on foodstuffs and consumer products (LGV), cosmetic products are broadly defined as "substances or preparations intended to come into external contact with certain parts of the human body, such as the skin, the hair system, the nails, the lips or external intimate regions, or with the teeth and the mucous membranes of the oral cavity, for the sole or predominant purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or influencing body odour" (the author's translation).

Cosmetic products must be safe, and the safety of the individual ingredients must be document-

ed in a safety report. References of any kind to disease-curing, disease-soothing or disease-preventing effects of cosmetics (eg, medicinal or therapeutic properties) are prohibited.

CBD has gained widespread popularity as an ingredient in cosmetic products in recent years. The use of synthetic CBD is not specifically regulated and can be used in the formulation of cosmetic products if the requirements set forth in the LGV are met.

Regarding the use of naturally derived CBD in cosmetics, (ie, CBD derived from the cannabis plant), the Implementation Guide provides as follows:

Article 54 (1) LGV refers to the list of substances prohibited in cosmetic products in Annex II of Regulation (EC) No 1223/2009 on Cosmetic Products, Entry No 306, which reads: "Narcotics, natural and synthetic: All substances listed in Tables I and II of the single Convention on narcotic drugs signed in New York on 30 March 1961". Schedule I of the signed Single Convention on Narcotic Drugs of 1961 (the Single Convention) lists cannabis, cannabis resin, cannabis extracts and cannabis tinctures. According to the definition in Article 1 of the Single Convention, "cannabis" means "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated". "Cannabis resin" is further defined in the Single Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant". The Implementation Guide goes on to conclude that, therefore, the use of "cannabis" or non-deresinated flowering or fruiting tops of the cannabis plant and products made from them (eg, hemp extracts, CBD) are prohibited in cosmetic products. Cannabis resin obtained from any part of the cannabis plant can also not be used to introduce CBD into cosmetics. Seeds and leaves not accompanied by the flowering or fruiting tops, however, can be used to produce cosmetics.

It should be noted that, on 19 November 2020, the European Court of Justice (ECJ) concluded in its judgment C-663-/18 (the Kanavape case) that CBD extracted from the fruiting or flowering tops of the cannabis plant, and not only from the seeds and leaves, "is not a drug within the meaning of the Single Convention". The ECJ clarified that "since CBD does not contain a psychoactive ingredient in the current state of scientific knowledge […] it would be contrary to the purpose and general spirit of the Single Convention to include it under the definition of "drugs" within the meaning of that convention as a cannabis extract".

Cosmetic ingredients have an international designation, a so-called INCI term (International Nomenclature for Cosmetic Ingredients). Each ingredient is also listed in the Central European Register of Cosmetic Ingredients (CosIng) either with or without restriction. Following the publication of the decision in the Kanavape case and upon request of the European Industrial Hemp Association (EIHA) to lift the existing restriction on the use of cannabis extracts in cosmetic products, the European Commission has lifted the restriction on CBD and has revised the entry as follows: "Cannabidiol – derived from extract or tincture or resin of cannabis". It recently did the same for cannabigerol, or CBG, which is another known minor constituent of cannabis. While the CosIng (cosmetic ingredients) database is not legally binding, the listing of ingredients is regarded by authorities and courts in the EU member states as a strong indication of their legality in cosmetic products.

While cannabis resin is clearly defined as a narcotic under Swiss law, cannabis extracts are

exempt from the NarcA if their THC content does not exceed 1%. In view of a harmonisation with recent practice in the European Union (EU) as well with the ECJ's conclusion that "it would be contrary to the purpose and general spirit of the Single Convention to include CBD under the definition of 'drugs' within the meaning of that convention as a cannabis extract", it would be desirable – and, in the author's view, in line with current legislation – to reconsider the described practice in the Implementation Guide to the effect that CBD, as well as all other cannabinoids, derived from cannabis extracts from the flowering and fruiting tops should also be allowed in cosmetic products.

### *CBD sold as utility articles*

CBD-containing liquids for e-cigarettes are classified as utility articles that come into contact with mucous membranes under the Federal Act on Foodstuffs and Utility Articles (Foodstuffs Act, FSA) as well as the LGV, may be sold unless they release substances in quantities that pose a risk to health. It is further not permitted to add CBD to liquids for e-cigarettes in pharmacologically effective doses.

Refill containers for e-cigarettes containing CBD are subjected to the provisions of the chemicals legislation. Distributors must carry out self-regulation and implement labelling and reporting obligations (product registration for chemicals).

On a side note, it may be added that paraphernalia and smoking accessories such as bongs, vaporisers, grinders (without CBD), etc, may be sold without restriction if they comply with the FSA, the LGV and the PrSG.

### *CBD sold as tobacco substitutes*

Hemp with a total THC content of less than 1% does not fall under the NarcA and can be sold as a tobacco substitute for smoking. Tobacco substitutes are a part of Swiss food legislation and are subject to the Tobacco Ordinance (TabV), independent of the Swiss Federal Tribunal's decision that hemp containing CBD is not considered a tobacco substitute according to the Tobacco Tax Act (TStG).

It is therefore lawful to sell tobacco substitutes containing CBD or other cannabinoids as dried flower, buds, or as cigarettes/cigars, for example. However, existing food legislation must be observed, which includes the obligation to self-regulate and to notify the FOPH before placing products on the market.

According to the TabV, tobacco substitutes must satisfy the prerequisites applicable to the smoked tobacco products they replace (eg, herbal cigarette packaging must contain photographic warnings). The substitutes must not pose a direct or unexpected threat to health.

### *CBD sold as foodstuffs*

Please see **3.2 Use of Non-controlled Cannabinoids in Food**, which includes some comments on the consumption of THC.

### *Reform of Switzerland's hemp seed legislation*

As of 1 January 2021, all provisions of the seed legislation relating to the production and sale of hemp seed and seedlings, which includes cannabis with a THC content of below 1%, were repealed. Previously, only approved varieties of hemp grown for oil and fibre that were listed in the Federal Office of Agriculture's (FOAG) varieties ordinance or the European Union's Common Catalogue of Varieties, which is still in force in the EU, could be placed on the market for commercial use in agriculture. This is a significant competitive advantage for Switzerland as an innovation hub for the development of hemp seeds and varieties as compared to the EU.

For the agricultural production of hemp, the provisions of the plant health legislation and the direct payments legislation must be respected. For the use of hemp as animal feed, the provisions of the Animal Feed Law must be observed.

## 1.2 Regulatory Authorities

Switzerland is a federal state, which means that powers are divided between the Confederation, the cantons and the communes, according to the principle of subsidiarity. The Confederation, in principle, only undertakes tasks that the cantons are unable to perform, or which are expressly allocated to the Confederation by the Federal Constitution.

As discussed in **1.1 Source of Regulations**, regulations affecting the cannabis market span a very wide spectrum of the law. It would go beyond the scope of this guide to describe the authorities responsible for enforcement on both a federal and cantonal level for each area of law. However, a short overview will be provided of the enforcement authorities in narcotics, therapeutic products, foodstuffs and utility articles (which includes cosmetics) and chemicals law.

### Enforcement of the NarcA

As a result of Switzerland's federal political system, the cantonal law enforcement agencies (ie, the public prosecutor's office) are principally charged with enforcing the NarcA, with the help of the police. The clear statement of the law that the enforcement of the NarcA lies within the competence of the cantonal law enforcement agencies was relativised by the fact that it had always been assumed that the narcotics sector was subject to special supervision by the Confederation. Consequently, the Office of the Attorney General of Switzerland could, under certain circumstances, order investigations itself if the criminal acts were committed in whole or in part abroad or in several cantons. This competence continues to exist. Thus, there is a parallel investigative competence of the Confederation in this area.

The Confederation exercises oversight over the implementation of the NarcA. It conducts controls at the border (import, transit and export) and in customs warehouses and bonded warehouses. The Confederation and the cantons work together to fulfil their tasks under the NarcA and co-ordinate their work. They may call on the assistance of other organisations concerned.

Non-compliance with the NarcA is a criminal offence. Under the NarcA any person who without authorisation, among others, cultivates, produces, stores, sends, transports, imports, exports or carries in transit narcotic substances, possesses, keeps, buys, acquires or otherwise obtains narcotic substances, etc, is liable to a custodial sentence not exceeding three years or to a monetary penalty.

As mentioned in **1.1 Source of Regulations**, medicinal cannabis products with a THC content of 1% and above may be prescribed with a special authorisation by the FOPH, which develops Switzerland's health policy and works to ensure that the country has an efficient and affordable healthcare system in the long term.

### Enforcement of the TPA

Swissmedic is responsible for the duties assigned to it by the TPA. It is involved in the entire life cycle of a medicinal product through its duties in the areas of authorisation, approval and monitoring of medicinal products. Swissmedic is run by the Confederation with the co-operation of the cantons, as an institution under public law with its own legal personality.

It is important to note that Swissmedic's areas of responsibility are closely related to those of other authorities or implementing bodies – for example, when it comes to the delimitation

between medicinal products and cosmetics or between medicinal products and foods, where the FOPH and the Federal Food Safety and Veterinary Office (FSVO) are involved, all areas relevant for the emerging cannabis market.

Furthermore, Swissmedic has, among others, the competence to authorise ready-to-use medicinal cannabis products and to grant a licence for imports of therapeutic products (including medicinal cannabis) if the applicant complies with the requirements of the Medicinal Products Licensing Ordinance.

In simplified terms and on a cantonal level, the Cantonal Office for the Control of Therapeutic Products (*Kantonale Heilmittelbehörde*) in Zurich, for example, is divided in three operative units: the inspectorate, the laboratory and the administration. The *Kantonale Heilmittelbehörde* in Zurich is responsible for the control of the production, wholesale trade and dispensing of therapeutic products, the market surveillance of therapeutic products (which includes marketability reviews and conformity tests in accordance with recognised pharmacopeias), the granting of cantonal licences for the dispensing of medicinal products (pharmacies, drugstores, etc), the issuance of professional and narcotic licences and other tasks. The cantonal pharmacy is mandated to secure a high quality and economical supply of therapeutic products to hospitals, a wide range of institutes and the general population. In the canton of Zurich, the cantonal pharmacy is also responsible for the production of a wide range of pharmaceutical products. Other cantons have similar structures.

In terms of enforcement, non-compliance with the TPA may lead to a series of administrative (including disciplinary) and penal actions on both the federal and cantonal level.

### Enforcement of the FSA

According to the LGV, business operators who manufacture, process, treat, distribute, import or export food, food additives or utility articles must exercise self-control and designate a responsible person who appropriately documents compliance with the requirements of the FSA/LGV. This includes the obligation to secure good manufacturing procedures, the implementation of quality management systems as well as the obligation to withdraw or recall unsafe food, if applicable.

The Swiss Association of Cantonal Chemists (ACCS) published a useful website listing local law enforcement authorities for food and utility articles in Switzerland; see www.kantonschemiker.ch. In Zurich, for example, the Cantonal Laboratory is responsible for the implementation of food safety regulation, including the control of reporting and permitting obligations, as well as the implementation of special protective regulations of non-food or utility articles such as cosmetics.

Authorities charged with the implementation of the FSA and its many ordinances have a wide range of administrative measures they can impose on non-compliant market participants.

## 1.3 Self-Regulation

While there are numerous organisations that act as self-regulatory bodies to the cannabis industry in Switzerland, three groups stand out in particular, as detailed below.

### The Interest Group Hemp (IG Hanf)

The association Interest Group Hemp (IG Hanf) represents the Swiss hemp industry and its members in politics, before authorities and in public. It is by far the largest interest group of market participants in the cannabis industry in the country. The association's goal is to promote exchange and co-operation among its members

and thus strengthen the hemp industry in Switzerland. Its mission is to establish cannabis in society in a sustainable manner and to create a regulated cannabis market in order to ensure that Switzerland plays a leading role in the global cannabis industry.

To secure quality control among its members, the IG Hanf established the quality label "Swiss Certified Cannabis". The label guarantees products and consumer safety and determines quality standards (in accordance with ISO 9001). Specifically, the goals of the label as stipulated in the guidelines of Swiss Certified Cannabis are:

- to guarantee absolute traceability throughout the production chain;
- to ensure highest security for consumers and customers;
- to build trust with consumers, customers and authorities;
- to protect against economic damage or loss of reputation.

The Swiss Certified Cannabis label can only be used by certified companies. The application process includes:

- training by a qualified auditor;
- a certification audit on site by an independent and qualified auditor;
- a decision on the granting of the certificate based on the audit report by the board of directors of IG Hanf.

The guidelines of Swiss Certified Cannabis set standards on quality policy, production, packaging, storage, safety, control, work-safety and hygiene, labour, environment and infrastructure.

### Swiss Society of Cannabis Medicine

The goal of the Swiss Society of Cannabis in Medicine (SGCM-SSCM) is to promote the acceptance of cannabis as a therapeutic product, its legal regulation as well as its clinical implementation in close co-operation with the FOPH. As an umbrella organisation for professionals from medicine, pharmacy, pharmacology, research and industry, its declared goal is to foster the scientific, rational and destigmatised use of medicinal cannabis as well as the simplified, unbureaucratic access to therapies with medicinal cannabis.

Its task is to serve as the Swiss interdisciplinary knowledge and information platform for the medical use of cannabis and cannabinoids and as a networking platform for a wide range of professionals, care-givers, interest groups, etc. The organisation further promotes basic and clinical research and collects valuable data, based on which it elaborates medical recommendations for the most relevant treatment principles. SGCM-SSCM is the Swiss ambassador of IACM (International Association for Cannabinoid Medicines).

### MEDCAN

MEDCAN advocates for the interests of patients in Switzerland who take cannabis as a medicine and provides information on the use and effects of the medicinal plant. The association pursues the goal of ensuring that patients in Switzerland have legal access to cannabis without a great deal of bureaucracy and can use it medically in tested quality and at reasonable prices. Moreover, it demands from the FOPH to further educate physicians regarding possible indications and dosages and to minimise the bureaucratic effort to obtain medicinal cannabis. MEDCAN advocates on a political and on a public level for people who use cannabis for medical purposes.

## 1.4 Key Challenges

The cannabis market faces tremendous challenges such as inconsistent cannabis and cannabinoids terminology, significant differences in

enforcement between cantons as well as a constantly changing regulatory environment.

The most obvious challenge market participants face is that cannabis is considered a narcotic drug if the THC content exceeds 1%. Consequently, all efforts by market participants to legally bring products to market are biased by the default assumption that cannabis is an illicit drug. This negative bias leads to heightened scrutiny by enforcement agencies and is not particularly conducive for an emerging new industry.

A practical example of a widespread confusion in the market is the classification of "CBD-pollinate". As mentioned in **1.1 Source of Regulations**, cannabis resin is defined in the Single Convention as "the separated resin, whether crude or purified, obtained from the cannabis plant". Cannabis resin is further separately listed in the BetmVV-EDI and is considered a controlled narcotic independent of its THC content. In contrast to cannabis resin, however, pollinate (hemp flower pollinate) consists of fine CBD hemp flower components that fall off when the biomass is shaken into drums (known as pollinators). The production of hemp flower pollinate is based exclusively on a process where the flower components of the cannabis plant, which are freely marketable, are extremely refined and extracted, resulting in a powder called hemp flower pollinate. At no point in this process is the resin content explicitly increased. The resin content (consisting of trichomes) of these products is the same as in CBD flowers. The resin is thus not secreted from the flower but is still in the very small flower components. Yet, many market participants had significant quantities of their pollinate production confiscated and destroyed, which has caused widespread legal insecurity and economic damage.

The classification of pollinate as cannabis resin is debatable and remains to be clarified by higher instance courts, or ideally by lawmakers. CBD-pollinate is often exported into the EU and contains in most cases a THC content of less than 0.2%. This is just one example of how confusing it can potentially be to bring cannabis products to market.

Furthermore, some of the most challenging aspects of the cannabis market come to the surface where various areas of the law overlap. The development of a new product can be very challenging when it is unclear, for example, whether it is governed by therapeutics or cosmetics law. A chewing gum containing CBD could be many things – for example, a therapeutic product, a cosmetic product or a foodstuff. Defining the product category and abiding by all regulatory requirements while considering pertinent case law can only be managed with a detailed technical and legal assessment.

Reference can be made to two very useful guides that can help, to some extent, navigate these complexities:

- Demarcation criteria therapeutic products – foodstuffs with regard to products to be taken orally (published jointly by Swissmedic and the FSVO); and
- Criteria for the demarcation of cosmetic products from therapeutic products and biocidal products (jointly issued by Swissmedic, the FOPH and the FSVO).

Another main challenge in the CBD market is the classification of cannabis extracts or tinctures (CBD oils). They can be qualified as raw materials or as ready-to-use products. While in practice, most consumers are ingesting CBD oils, such oils cannot be marketed as foodstuff or nutritional supplements without authorisation of its components as novel food by the FSVO or the European Commission (EC). No company

in Switzerland, or in the EU, has obtained such authorisation to date.

Another key challenge for participants in the medical cannabis market is to place a medicinal cannabis product on the market. In view of the revision of the NarcA – which is thoroughly described in the adjacent **Trends & Developments** article – and the lifting of the traffic ban for cannabis for medicinal purposes, the market for medicinal cannabis should be better accessible for companies in the future.

The above examples of key challenges do not touch on the many complexities surrounding international trade of medicinal and recreational cannabis products, and a whole range of other issues and uncertainties participants in the cannabis market must deal with.

### 1.5 Level of Regulation

Cannabis-specific regulations in Switzerland are, with few exceptions, limited to narcotics and criminal law. Legal uncertainty is still prevalent in production, trade and consumption of cannabis products of all kinds (cosmetics, foodstuffs, medicines, recreational use, etc), as is inconsistent cantonal enforcement.

In other jurisdictions, such as in many US states where medical and recreational cannabis have been legalised, the cannabis market is thoroughly regulated. Countries such as Canada and Uruguay are following suit with their own regulatory models.

Considering these developments, a revision of Switzerland's approach to cannabis regulation appears warranted, as was recently proposed in a postulate submitted to the Council of States on 18 March 2021 by Thomas Minder, a member of the Council of States. Specific cannabis-related legislation could bring legal certainty throughout the value chain and secure efficient quality control measures. An allocated taxation of cannabis products could generate state revenues and secure the financing of already necessary prevention and health measures, in particular for the protection of youth.

At the same time, cannabis legislation concerning specifically THC limits in Switzerland is considered rather progressive if compared to the EU and the USA, where the threshold from legal cannabis (or hemp in the USA) to a narcotic drug (which in some states in the USA is legalised) is passed when the THC levels surpass 0.2% or 0.3%, respectively. Also, the Ordinance on the maximum levels of contaminants (VHK) allows for significantly higher values of THC intake from food than the THC values in the EU. Switzerland has further repealed all provisions of the seed legislation relating to the production and sale of hemp seed and seedlings and is no longer bound by the European Union's Common Catalogue of Varieties.

In view of the latest developments in legislative reform of the NarcA regarding medicinal cannabis as well as cannabis trials for recreational purposes, Switzerland is well positioned to further expand its regulatory edge in the emerging European cannabis industry.

### 1.6 Legal Risks

Companies and individuals in the cannabis market must navigate a complex web of interrelated, constantly changing areas of law. Non-compliance with existing laws and regulations may lead to indictments for criminal offences, to administrative penalties and potentially to civil damage claims.

Recent enforcement measures by authorities were, for example, the shutdown of a retailer's website for publishing health claims in connection with CBD products, or the imposition of a marketing ban for specific CBD oils.

It should be noted that special attention must be paid to compliance with the NarcA. Cannabis resin is illegal independent of its THC content. Furthermore, cannabis products with a total THC content below 1% must meet the specific requirements of the Therapeutic Products Act, the Foodstuffs Act, the Ordinance on Foodstuffs and Utility Articles, the Chemicals Ordinance and the Tobacco Ordinance, among others, depending on the classification of the product placed on the market. It should be noted in this context that not only the NarcA but also other acts such as the TPA provide for penal provisions.

### 1.7 Enforcement

Please see **1.4 Key Challenges**.

## 2. CROSS-JURISDICTIONAL ISSUES

### 2.1 Cross-Jurisdictional Standards

In Switzerland, only cannabis with a THC content below 1% can be exported. The cannabis legislation of the importing country must therefore be complied with. Generally, in the EU, cannabis-products with a THC content of 0.2% and above are considered narcotic drugs and thus cannot be imported, except for medical purposes with a special permit from local authorities.

A revision of the NarcA which was adopted on 19 March 2021 will allow for exports of medical cannabis with a THC content of 1% and above. It is estimated that the revised law will be enacted in the summer/autumn of 2022. Further details can be found in the adjacent **Trends and Developments** article.

Importers of cannabis products with a THC content of 1% and below must be able to provide proof in the form of a batch-specific analytical certificate for the delivery in question issued by a laboratory accredited to ISO/IEC 17025 or by a GMP laboratory.

## 3. FUTURE DEVELOPMENTS

### 3.1 Legal Elements Affecting Access to Medical Cannabis

The main elements affecting medical cannabis in Switzerland are described in the adjacent **Trends and Developments** article, along with an overview of impending changes to the current regulatory framework.

### 3.2 Use of Non-controlled Cannabinoids in Food

The FSA sets forth the rules on the safety and transparency of foodstuffs and utility articles. According to the FSA, foodstuffs are all substances or products that are intended or may reasonably be expected to be consumed by human beings in a processed, partly processed or unprocessed state. Medical products, narcotics and psychotropic substances do not fall under the definition of foodstuffs, and the other way around.

Except for a few reservations (eg, “novel foods”), non-described foods without an authorisation can be placed on the market, provided they meet all the requirements of food law.

Under certain circumstances, which will be described below, cannabis products may also be used in foodstuffs. The main tenet in foodstuffs law is that foodstuffs must be safe – that is, they must neither be harmful to health nor unsuitable for human consumption.

#### Novel Foods

For foodstuffs that have not been used for human consumption to any significant extent either in Switzerland or in an EU member state

before 15 May 1997, so-called "novel foods", an authorisation by the Federal FSVO or an approval by the European Commission (EC) is required. This applies to extracts of *Cannabis sativa L.* that contain cannabinoids such as cannabidiol (CBD) and food products enriched with extracts of *Cannabis sativa L.* or with cannabinoids such as CBD (eg, hemp seed oil with added CBD, food supplements with CBD), which are classified as novel foods and therefore require an authorisation.

Products of *Cannabis sativa L.,* or parts of plants that had a safe and documented significant use as food in the EU before 15 May 1997, are not considered novel foods in Switzerland provided they originate from an approved plant of *Cannabis sativa L*. This is particularly the case for hemp seeds, hemp seed oil, hemp seed flour and defatted hemp seeds.

Furthermore, in Switzerland, herbal tea made from leaves of the hemp plant *Cannabis sativa L.* is also not considered a novel food. However, the production, import or market placement of herbal teas obtained from the herb of the cannabis plant is possible if one furnishes proof that the herbal tea was already consumed as a foodstuff to a significant degree prior to 15 May 1997, and is therefore not classified as a novel food. Novel foods that do not require an authorisation are listed in the FDHA Ordinance on Novel Foods.

### Authorisation

As part of the authorisation procedure for novel foods, the FSVO examines whether the product is safe and not deceptive. The basic prerequisite for approval is that the product is classified as a foodstuff and is not covered by the legislation on medicinal products. In the case of foodstuffs containing cannabis, the Ordinance on the maximum levels of contaminants (VHK) is relevant. It regulates the maximum permissible levels of delta 9-tetrahydrocannabinol in foodstuffs (which are generally higher than in the EU).

It is important to note that all foods which in accordance with the Novel Food Regulations (EC) No 258/97 and (EU) 2015/2283 may be placed on the market in the EU are fundamentally also marketable in Switzerland (except for genetically modified foods). To place foodstuff with CBD on the European market presupposes the application for authorisation to the European Commission. If the application is granted, foodstuff containing CBD can be also placed on the Swiss market. Hence, the authorisation from the European Commission entails the advantage that the foodstuff can be placed on both the European and the Swiss markets. However, the reverse situation does not apply. Foodstuffs that are not novel foods in Switzerland or have been authorised as such in Switzerland and are classified as a novel food in the EU require an authorisation from the European Commission for market placement in the EU.

Lastly, authorisations are generally not issued for composite foods. The authorisation requirement always relates to a substance, not to a composite product containing a novel food as an ingredient.

### The EIHA Consortium

The European Industrial Hemp Association (EIHA) is Europe's largest association that represents the common interests of hemp farmers, producers, and traders working with hemp fibres, shives, seeds, leaves and cannabinoids.

In 2019, EIHA created a Novel Food Consortium with the aim of submitting a joint Novel Food application both to the UK Food Safety Authority for the British market as well as to the European Food Safety Authority (EFSA) for the EU market (which, as mentioned above, would include Switzerland), the costs of which will be shared

among its members. It is estimated that the consortium will invest up to EUR3.5 million for financing all relevant and unprecedented toxicological studies on CBD and THC with the help of a qualified service provider (ChemSafe). A whole range of cannabinoids containing ingredients will be tested to secure all food products using these ingredients will be covered by the joint application. For the purpose of the application, a corporation under German law was founded (EIHA projects GmbH), which collects the special contributions to finance the project and ultimately acquires the rights for the distribution of the approved products. EIHA projects GmbH will manage these rights and transfer them to EIHA members, with an established sublicensing system for white label (retail) trading companies.

In its press release dated 23 March 2021, EIHA informed its members that the UK Food Safety Authority has confirmed that both applications for the regular/full-spectrum and the natural isolate products were considered to be compliant with the administrative requirements. By granting the pre-validation status, the Food Standards Agency recognises and supports the strong will of the hemp sector, and particularly of the EIHA Consortium, to evaluate and determine the safety levels of its novel food products.

Swiss companies aspiring to develop and bring cannabis-based food products to market are advised to evaluate a participation in the EIHA Consortium.

### 3.3 Decriminalisation or Recreational Regulation

The latest developments regarding a potential legalisation of cannabis use for recreational purposes can be found in the adjacent **Trends and Developments** article.

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# Trends and Developments

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The current regulatory environment surrounding cannabinoid-based products in Switzerland is unfortunately still marked by a high degree of uncertainty, due both to vague legislative requirements and heterogenous, sometimes arbitrary, enforcement. However, with the rise of public awareness of the general benefits of the cannabis plant as a result of the cannabidiol (CBD) boom of the last few years, as well as by actual and growing anecdotal evidence from local and liberalised recreational markets such as Canada, Uruguay and certain states in the USA, recent legislative developments are presenting an opportunity for Switzerland to establish itself as a role model for an innovative, pragmatic, safe and comprehensively regulated cannabis market.

## Medical Cannabis Reform

### *The status quo*

A study conducted by the Institute for Addiction and Health Research on behalf of the Federal Office of Public Health (FOPH), the findings of which were published in February 2020, came to the conclusion that, for over 96% of the participants questioned, the consumption of medical cannabis has led to an improvement of their symptoms. Half of the participants reported an "extreme improvement". A large part of the participants who already had prescriptions for cannabinoid-based medicines reported that they were able to either completely abandon other prescribed drugs, or at least substantially reduce their consumption. See Cannabiskonsum: Rekreative oder medizinische Beweggründe?

Around 3,000 patients are legally prescribed medical cannabis in Switzerland today. Meanwhile, the FOPH estimates that over 110,000 patients are consuming "medical" cannabis illegally (ie, sourced from the black market), which exposes them to significant health risks due to the lack of quality control and a growing number of cut and contaminated products in circulation. This number does not include those who consume cannabis for recreational purposes, which is, by conservative measures, three times that of the FOPH estimate.

Cannabis with a tetrahydrocannabinol (THC) content of 1% and above is considered a prohibited narcotic in Switzerland. Under very restrictive circumstances, cannabis with a THC content above 1% may be prescribed for medical purposes, which requires an exceptional permit from the FOPH. As the currently most-researched cannabinoid, THC is predominantly used for chronic pain conditions, spasticity and spasms, as well as nausea and loss of appetite (mostly in the context of chemotherapy). Ready-to-use medicinal products may only be marketed in Switzerland if they are approved by Swissmedic, the Swiss Agency for Therapeutic Products. Only one ready-to-use medicinal product with a THC content above 1%, Sativex®, is fully approved in Switzerland. Sativex can be prescribed without special permit for spastic convulsions in multiple sclerosis patients. For any other indication, an exception permit by the FOPH must be obtained (ie, for so-called off-label use).

If an approved preparation is unsuitable, physicians can prescribe cannabis as a drug which is exempt from approval by Swissmedic but which still requires a special permit by the FOPH. The drug is then usually produced by a pharmacy on a doctor's prescription as a so-called extem-

poraneous preparation (ie, a "formula magistralis"), which is how most cannabis is prescribed in Switzerland today.

Applying for a special permit at the FOPH is burdensome, both for the physician and the patient. Although most applications are granted, the surge of applications in the last few years no longer justifies the special treatment of medical cannabis as a prohibited narcotic. This realisation has led to a revision of the current regime and the required amendments to the Federal Act on Narcotics and Psychotropic Substances (NarcA), which the Swiss Parliament recently adopted (on 19 March 2021). It is estimated that the revised law will be enacted in the summer/autumn of 2022 at the earliest, together with the details of implementation in a separate Ordinance.

### *The amendment of the NarcA*

The main features of the legislative amendment are as follows.

- The ban on the marketability of medical cannabis will be lifted. Medical cannabis will be reclassified as a controlled narcotic with restricted marketability. Cultivation, processing, production and trade will be subject to the authorisation and control system of Swissmedic, in the same way as other narcotics that are used in a medical context (eg, morphine).
- A special permit by the FOPH will no longer be required to prescribe medical cannabis. In other words, every doctor in Switzerland will be able to prescribe medical cannabis.
- During the first few years after the coming into force of the amendment, doctors will have to regularly report to the FOPH a whole range of data regarding the therapies. The data collection will serve as a basis for the scientific evaluation of the revision as well as guidance to the responsible cantonal enforcement authorities and the prescribing physicians.
- Commercial exports of medical cannabis will be made possible.

### *Reimbursement by compulsory health insurance*

Unfortunately, treatment with medical cannabis products is not covered by the compulsory health insurance (OKP) due to insufficient scientific evidence regarding the efficacy and cost-effectiveness of these medicines, especially for extemporaneous preparations. Such medicines are reimbursed by the health insurance providers in consultation with the physician on an exception basis only.

The major challenge regarding the adopted amendment is that the law does not envisage adjusting the current requirements for reimbursement by the OKP. According to MEDCAN, Switzerland's largest medical cannabis patients' association, the costs of treatment with medical cannabis can range from CHF450 to over CHF10,000 per month.

A Health Technology Assessment (HTA) report is being prepared on behalf of the FOPH to clarify the scientific evidence regarding the efficacy and cost-effectiveness of medical cannabis products and to differentiate between the various patient groups. The HTA will form the basis for the reimbursement decision on medical cannabis products that do not require a marketing authorisation. It may be published later this year.

### *Commercial opportunities*

The amendment to the NarcA presents entrepreneurs with a range of new and exciting commercial opportunities, such as:

- cultivation of medical cannabis in Switzerland (with a special permit by Swissmedic when the amendment has been enacted);

- further research into new plant varieties and traits as well as cannabinoid development;
- innovative research and development of cannabinoid-based drugs;
- development of new delivery methods, including vaporisers, dry powder inhalers, slow-release tablets;
- establishment of a cross-border medical cannabis marketplace with a surge in imports as well as exports;
- development of software tools for quality assurance, seed-to-sale traceability solutions as well as documentation standards (GACP, GMP, etc);
- education platforms for physicians, patients and the general public.

Many more opportunities will arise in this growing and fast-moving industry. The success of the adopted amendment, the purpose of which is first and foremost a facilitated access to medical cannabis for patients, will hinge on whether these patients will be able to obtain reliable, quality-controlled, safe and affordable medical cannabis products.

### Tiptoeing in Cannabis Legalisation: Recreational Pilot Trials

Cannabis is the most frequently consumed illegal substance in Switzerland. Around one-third of people aged 15 and over have already had experience with the drug. According to the FOPH and Addiction Monitoring Switzerland, approximately 7.7% of the population used cannabis at least once during the last 12 months, and 4% in the last 30 days. See Cannabis Use – Basic Facts and Figures, and Addiction Monitoring in Switzerland.

Repression has never been effective in curbing cannabis consumption or in eliminating the black market. Legislators in Switzerland have therefore arrived at the conclusion that alternative regulatory options must be examined. At its meeting on 31 March 2021, the Federal Council adopted the Ordinance on Pilot Trials as per the NarcA, which sets a detailed framework for the dispensing of cannabis products for non-medical use. On 15 May 2021, an amendment to the NarcA came into effect, allowing pilot testing of the controlled dispensing of cannabis for recreational purposes. From this point onwards, applications to conduct such trials can be submitted to the Federal Office of Public Health.

The amendment to the NarcA, which will remain in effect for ten years, provides the legal basis for the implementation of local and time-limited scientific pilot trials with cannabis. The pilot trials will allow consumers to legally purchase a wide range of cannabis-based products. The cannabis offered must meet high quality standards with strict seed-to-sale transparency and must originate from organic cultivation.

The aim of the studies is to expand knowledge on the advantages and disadvantages of controlled access to cannabis. They should facilitate the examination and documentation of the consequences on health and consumption habits of users in a scientific framework and provide data on the effects on the local illicit drug market as well as on the protection of minors and public safety.

In more detail, the pilot trials must meet the following main requirements.

- Pilot trials are limited in time (five years, with an option to extend by another two years), location (one or several municipalities), as well as number of participants (maximum 5,000 participants per trial).
- Cannabis supplied to the pilot trials has to originate in Switzerland, be in line with the guideline on good agricultural and collection practice (GACP) of the European Medicines Agency (EMA), and be, in principle, organi-

cally produced according to the Organic Farming Ordinance of 22 September 1997 (only outdoor or greenhouse production that is soil-bound – ie, indoor grow is excluded).
- The total THC content of any dispensed product may not exceed 20%; in products for oral intake the THC content may not exceed 10 mg per serving. Cannabis products must not contain levels of contaminants that give rise to health concerns and must be limited to specified amounts of foreign components, microbial contaminants, mycotoxins, heavy metals, pesticides and solvent residues from extraction. Notably, the maximum levels of delta-9-THC content as per Annex 6 of the Contaminants Ordinance of 16 December 2016 do not apply to edibles.
- Cannabis products must abide by a whole set of safe packaging and labelling requirements.
- Advertising for cannabis products remains prohibited.
- Minors (under the age of 18) are excluded from the pilot trials and participants must already be consumers of cannabis products.
- The maximum amount of dispensed cannabis per participant per month may not exceed 10 g of total THC.
- Cannabis products may only be dispensed at points of sale with trained staff and adequate infrastructure, and at a price that is in line with the black market. Distribution will therefore be made possible in both pharmacies and social clubs, for example.
- Both public and private organisations can apply to the FOPH to conduct cannabis trials.
- Outside of the pilot trials, the existing cannabis prohibition with the associated penal provisions for violations of the law will continue to apply.

A long list of further requirements is detailed in the Ordinance on Pilot Trials as per the NarcA of 31 March 2021.

### *Indoor or outdoor production?*

While the adoption of the pilot trial legislation has been positively received by the cannabis industry and is recognised as a possible further step towards a controlled liberalisation, the requirements for the cannabis products to be used in the trials poses some major challenges of which lawmakers may not have been fully aware. Most of the cannabis from the black market consumed today is produced indoors. In general, the cannabis flower grown indoors in a controlled environment tends to be denser, contain a higher trichome count and provide a more potent "high" than cannabis grown outdoors or in greenhouses, although this point is subject to repeated debate in the cannabis community.

Concerns have been raised that the requirements set with regard to organic farming, which limits suppliers of the cannabis trials to soil-bound outdoor production or greenhouse operations, may thwart obtaining reliable data from the trials by failing to attract enough participants willing to try a new avenue with products to which they are not accustomed. Other challenges may be to abide by a precise THC limit of 20% when growing outdoors where weather conditions cannot be controlled, as well as the use of clones only as opposed to "feminised" seeds which are not compliant with the Organic Farming Ordinance but have grown popular as they can be relied on to produce female plants only and increase yield.

It should be noted that no such restrictions have been imposed on cultivation of cannabis for medical purposes.

### *Commercial opportunities*

The high bar set regarding the application process, cultivation, production, distribution and data-gathering of recreational cannabis products in the context of the trials, as well as the black-market pricing ceiling, will leave very limited room for extracting meaningful margins for

suppliers or distributors of the pilot programme. While the pilot trials allow for up to 5,000 participants, the first impressions obtained by universities and cities planning to conduct such trials is that the actual number of participants will be significantly lower (ie, in the hundreds at best), mostly for funding reasons. However, the trials may well be a first step towards a trend in further liberalisation of the recreational cannabis market. Companies with a reliable, quality-controlled supply chain may be well positioned to use the pilot trials to establish brand equity, create innovative new products and gather valuable experiences in a new and developing market.

### Further Political Developments

#### *The Siegenthaler Initiative*

On 25 September 2020, Heinz Siegenthaler, a member of the Swiss National Council, filed a parliamentary initiative which was signed by a total of 40 members of the Swiss National Council, in an attempt to force a new and comprehensive regulation for the cultivation, production, trade and consumption of cannabis containing THC, in line with the recommendations of the Federal Commission on Narcotic Drugs (EKSF). The main objectives of the initiative are the control of production and trade by governmental bodies, the separation of the medical and the non-medical markets, the drying-up of the black market by lifting the prohibition, the regulation of taxation and advertising as well as cultivation for personal use.

The reasoning accompanying the original text of the initiative describes a general moral and legal inconsistency in cannabis prohibition based on current scientific research, especially if contrasted with other harmful substances such as tobacco and alcohol. The Federal Council, in a statement made on 23 May 2018, candidly admitted that the NarcA has failed to fulfil its purpose of protecting the population, considering the more than 300,000 regular cannabis consumers in Switzerland. A flourishing black market, the lack of quality controls and reliable information, the ineffective protection of youth, as well as a growing risk of "cut" cannabis products containing artificial and toxic substances warrant the replacement of the current prohibition with a fully regulated cannabis market that meets the requirements of Swiss addiction policy, according to the initiative.

On 28 April 2021, Switzerland's Health Commission of the National Council voted in favour of a controlled legalisation of cannabis. This is the first important political hurdle the Siegenthaler parliamentary initiative has passed. As a next step, the equivalent commission in the Council of States will review the dossier.

This latest political development surrounding cannabis legislation is proof that the urgency to comprehensively regulate this growing market has manifested itself in the general public consciousness. The limited view of cannabis as an allegedly harmful narcotic drug and the stigmatisation of its consumers is making way for the recognition of its significant medical potential, as well as the promising economic growth it could further unfold in recreational and industrial use.

Given its already progressive regulatory framework regarding THC thresholds compared to the rest of Europe and the liberalisation of cannabis for medical purposes, Switzerland is in an excellent position to expand its lead in Europe as an innovative, responsible and attractive hub for cannabis entrepreneurs all along the value chain.

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