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Life Sciences

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# Regulation of Cannabis Products in Switzerland – New Developments

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## Key Take-aways

- 1.** Companies generate significant turnover on the liberalized cannabis market. Swiss regulations concerning cannabis products are partly less strict than abroad.
- 2.** The market for cannabis products nevertheless remains closely regulated in Switzerland. Companies must keep an eye on the regulatory and criminal law risks.
- 3.** New opportunities are opening up in the Life Sciences sector in Switzerland with the facilitation of access to cannabis medicinal products. In the medium term, a liberalization of recreational use is also possible.

## 1 Opportunities for Companies

**Trade in cannabis products** has been predicted to have high market potential in Switzerland for some time. Life sciences start-ups as well as listed pharmaceutical companies and investors are increasingly interested in the market. In the U.S. and Canada, trade in cannabis products has grown into a billion-dollar industry. In Switzerland, too, **regulatory ease-ments** are causing the market to grow. The latest development is liberalized access to cannabis medicinal products. In the spring of 2021, the Swiss Parliament passed a corresponding amendment to the law, which came into force together with the implementing provisions on August 1, 2022. At present, therefore, opportunities are opening up for companies in the pharmaceutical sector to position themselves early with their own products on the growing market with cannabis products.

At the same time, companies must keep an eye on the legal risks. In Switzerland, cannabis products are closely regulated. In particular, restrictions under criminal law, the multi-layered regulation of the industry, the fact that different authorities are responsible depending on the product category, and different approaches in cantonal enforcement can lead to uncertainties.

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**Cannabis products that have a THC content of more than 1 % are prohibited.**

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## 2 Criminal Law Risks

The hemp plant commonly referred to as cannabis contains a variety of cannabinoids, of which **THC** (tetrahydrocannabinol) causes psychotropic effects. For this reason, cannabis is classified as a prohibited narcotic in Switzerland, depending on its composition. When dealing with cannabis products, potential **risks under criminal law** must therefore also be considered.

Cannabis products with a **THC content of more than 1%** are prohibited. This limit is more liberal than, for example, in the EU or the USA. In principle, cannabis may not be cultivated, produced, imported, dispensed, sold, or consumed. The prohibition applies irrespective of the intended use and, in addition to hemp seeds and hemp plants, also applies to all objects and preparations that have a total THC content of at least 1 %, or are produced from hemp with a total THC content of at least 1 %. Cannabis resin (hashish) is (at least currently) generally prohibited, even if it contains less than 1 % THC.

In addition to THC, the hemp plant contains a variety of other cannabinoids, including cannabidiol (**CBD**), which, unlike THC, is not subject to the Narcotics Act due to its lack of psychoactive effects. As certain positive properties (e.g. calming and anti-inflammatory effects) are also attributed to CBD, products containing CBD have been popular for several years.

In summary, cannabis should **not be regarded as a generally prohibited product under criminal law**, but a distinction must be made in each individual case as to which part of the plant is used for which purpose and with which composition of substances. In the cultivation and production of cannabis products, the ingredients and THC content of the products should therefore be professionally monitored and carefully documented. Swiss authorities can carry out checks in this regard at any time and confiscate products.

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**Access to cannabis medicinal products has been facilitated since August 1, 2022.**

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## 3 Regulatory Requirements for CBD Products and Products with Low THC Content

In Switzerland, a wide range of CBD products with a **total THC content of less than 1%** are offered that are permitted under narcotics law, such as hemp flowers, fragrance oils, food supplements, foodstuffs, tobacco substitutes, or cosmetics. For the production and distribution of such products, a large number of **regulatory requirements** have to be considered. Assignment to a product category (e.g., drug, food, cosmetic, chemical) is based on the individual case and depends on various characteristics such as composition, intended use, dosage, promotion, etc. Depending on the assigned product category, different laws and ordinances are applicable, and different authorities are competent for the enforcement or the issuance of licenses. If the classification is not clear and no special law is applicable, the Product Safety Act applies as catch-all legislation. Overall, the regulation of cannabis products is complex, and its application in individual cases is sometimes difficult to predict.

When exporting cannabis products abroad, it is important to bear in mind that due to sometimes stricter regulations and different limits for THC in cannabis products, there is a risk of criminal prosecution abroad, or at least problems may arise when importing into the respective country.

## 4 Facilitation of Access to Cannabis Medicinal Products

A **cannabis medicinal product** is a cannabis-based narcotic with a standardized active ingredient content. It must meet the legal requirements for safety and quality and be intended for medicinal use. At present, there is only one ready-to-use me-

dicinal product with the active ingredient THC (Sativex® for the treatment of spastic convulsions in multiple sclerosis) that has been approved in Switzerland under therapeutic products law. If the approved preparation is unsuitable for the treatment, doctors can also prescribe cannabis as a drug that is exempt from authorization. Most medicinal treatments are currently not carried out with ready-to-use cannabis medicinal products, but with cannabis preparations that are manufactured by a pharmacy on a doctor's prescription (so-called extemporaneous preparations).

Until recently, due to the comprehensive prohibition of cannabis, the **medicinal use of cannabis** with a total THC content of more than 1 % was only possible in individual cases and with an exceptional permit. However, in recent years interest in cannabis rose sharply due to its potentially wide range of uses and positive reports on its therapeutic qualities. The demand for exceptional permits was correspondingly high, for example for the treatment of chronic pain conditions, neurological diseases, or the consequences of chemotherapy. The Federal Office of Public Health issued approximately 3,000 exceptional permits annually.

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## The export of cannabis for medicinal purposes is now also permitted.

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In spring 2021, the Federal Assembly adopted an **amendment to the law in order to facilitate access to cannabis medicinal products**. The amendment to the law and its ordinances entered into force on August 1, 2022.

With the amendment to the law, cannabis for medicinal purposes is classified as a narcotic with restricted marketability. The cultivation, processing, and marketing of cannabis for medicinal purposes is now subject to the authorization and control system of the Swiss Agency for Therapeutic Products (Swissmedic) under narcotics law (as was already the case for other narcotics used for medicinal purposes, such as morphine). The responsibility for medicinal treatment with cannabis medicinal products lies with doctors.

Anyone cultivating cannabis for medicinal purposes requires an **operating license**. Applicants must be entered in the Swiss commercial register and must ensure the storage of the controlled substances and protection against theft and misappropriation of the goods. Furthermore, a person responsible for compliance with the legal provisions on narcotics must be designated. In addition to the operating license, an **individual cultivation license** is required prior to each cultivation. Applicants must explain the type and extent of cultivation and its specific use and prove that they have a quality control system that also enables tracking of the cultivated plants.

Cannabis medicinal products can now be dispensed on a **doctor's prescription**. Treating physicians decide independently on the type and scope of medicinal treatment within the scope of their professional duties of care. Obtaining

an exceptional permit is no longer required. Self-medication with cannabis medicinal products outside of medicinal treatment remains prohibited.

The revised legislation also allows the export of cannabis for medicinal purposes.

With this amendment to the law, the Swiss Confederation wants to make better use of the potential of cannabis as a medicine and eliminate the contradiction between the increasing medicinal use of cannabis and its classification as a prohibited narcotic. This opens up a new market for manufacturers.

## 5 Liberalization of "Recreational Use" of Cannabis?

A trend toward liberalization is also emerging in Switzerland for the **non-medicinal, "recreational use"** of cannabis. The black market in cannabis generates an estimated annual turnover of over 500 million Swiss francs in Switzerland. When products purchased on the black market are consumed, there is a risk that they may contain dangerous harmful substances or synthetic cannabinoids. At the suggestion of various cantons, the Swiss Confederation is therefore currently looking for a middle way between prohibition and complete legalization of cannabis. In the fall of 2020, Parliament inserted an "experimental article" into the Narcotics Act (Art. 8a NA). The Federal Council issued an implementing ordinance to this effect. The provisions have been in force since May 15, 2021.

Under that provision, pilot projects may be conducted over the next few years to test the health and socioeconomic influences of certain legalization or regulatory steps in the controlled dispensing of cannabis for non-medicinal use by adults. This approach is intended to provide a sound scientific basis for possible decisions on the liberalization of cannabis regulation.

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## In the medium term, recreational use could also be liberalized.

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## 6 Outlook

For some years now, the **emergence of new cannabis markets** for products with a low THC content (below 1 %) and for CBD products could be observed in Switzerland. This has led to the development of new production, processing, and distribution chains for cannabis in Switzerland. Internationally, the cannabis products market is also developing into an industry with significant sales. With the recent liberalization of cannabis medicinal products, further opportunities are opening up for economic players in Switzerland, especially in

the life sciences sector. In the medium term, the market for the recreational use of cannabis could also open up. However, when operating in the field of cannabis products, it is important to keep in mind that this is a highly regulated market. It is therefore essential to ascertain the legal risks in advance when developing, producing, and distributing cannabis products and financing them, and to integrate robust quality and safety measures into operational procedures. It is safe to assume that there will be further legal developments in this sector in the coming years.



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