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Peter Homberg, Partner and Head of Dentons German Life Sciences practice, gave insights about the recent legalization of medical cannabis in Germany in *LABIOTECH.eu*, a leading digital portal for news in the European biotech-industry. The German Parliament judged in March, that cannabis can be used and cultivated for medical use from now on. Homberg comments on this decision and compares with opinions from other EU-countries on this matter, giving an overview of the current legal situation in the European Union.

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In March 2017, the German parliament voted for the legalization of cannabis for medicinal purposes. This meant that many changes had to be made within its legislation. A year on, much has changed in this respect. Moreover, other EU member states have been closely monitoring Germany's progress in the legalization of medical cannabis and are now following suit.

When the cannabis plant, *Cannabis sativa*, is legalized for medical use, this means that authorities allow the distribution of therapeutics that contain tetrahydrocannabinol (THC) – the key psychoactive ingredient in cannabis. This includes cannabis extract in mouth sprays, dried cannabis flowers for brewing in tea or vaporizing, or capsules containing THC.

The legalization process in Germany has been strictly performed and controlled by the government. Law firms, on the other hand, are responsible for advising companies, who want to import, cultivate and distribute cannabis in Germany.

We have caught up with Peter Homberg, Partner and Head of the German Life Sciences Practice at Dentons. Dentons is one of the top 10 global law firms and present in over 50 countries. For the past few years, Peter and his team have been monitoring the legalization process for medical cannabis closely. They have been watching the developments in German legislation and the pharmaceutical market, and advised and informed their clients on regulatory issues of import and future cultivation of cannabis in Germany.

Peter has spoken to us about the latest developments in Germany in regards to medical cannabis, and the effect Germany's change of heart has had on other EU member states. Namely, countries such as Denmark and Portugal, who are taking their first steps towards legalizing cannabis for medical use.

### **The legalization of cannabis for medical use has experienced a widespread wave of interest and support in Europe. Why is this topic becoming so important now, within governments and the scientific community?**

Although Germany has one of the strictest narcotic laws in Europe, it changed its mind on medical cannabis last year. The German parliament voted that cannabis could not only be used for medicinal purposes, but also be cultivated within the country under strict regulations.

In a domino-like effect, the governments of several other EU member states have started thinking about the

legalization of medical cannabis as well. As Germany is one of the largest economies in Europe, other countries can also see the positive impact this legalization process has had on its economy and its patient community.

## **In 2017, the German parliament voted for the legalization of cannabis for medical use. What is the current state of affairs in regards to the legalization process?**

Since the legalization of cannabis for medical use, a number of laws have been adjusted. The majority of these changes were implemented in March 2017 and when it comes to the legislation, there are no matters outstanding. However, specific regulations still need to undergo a certain refinement, as they came into discussion after the legalization.

The import of irradiated cannabis, for instance, is still being discussed. Whereas one side argues that this process allows for the complete elimination of mould from cannabis leaves, the other argues that it might not be safe for patients. What's more is that the German authorities have yet to decide whether cannabis counts as a raw material or a pharmaceutical. A lot of regulations and approvals depend on that decision.

The next step in the legalization process is the granting of per-lot licenses for companies to grow and distribute cannabis. Overall, 10 licenses will be distributed to a small number of companies. At Dentons we are closely monitoring this process and advising our clients in regards to regulatory affairs and tender processes.

Before cannabis was legalized for medical use in Germany, patients who needed cannabis had to apply for a specific exemption at the Federal Institute for Drugs and Medical Devices (BfArM). The regulations were very strict, so only about 700 people were granted the permission to use medical cannabis.

To date, Germany's top 3 health insurance companies have already received approximately 13.000 applications for reimbursement for the use of medical cannabis. This already shows the economic impact that the legalization of cannabis for medicinal purposes has and will have on the German market.

## **Although the effects and use of cannabis are highly controversial, there is growing evidence that it can impact patients' quality of life. What is the significance of cannabis for patients specifically?**

For medical purposes, cannabis can be used, for example, as an alternative for other pain therapies, which may not be working or have strong side effects. People with chronic pain, for example, often experience strong side effects from their pain medications. These can be alleviated with cannabis.

Amongst other indications, cannabis may also relieve symptoms of cancer patients and multiple sclerosis patients. It contains THC. That is the component it is most famous for. THC binds to specific receptors in the human central and peripheral nervous system called cannabis receptors (CB). For example, if THC binds to CB1 in the spinal cord, this reduces the perception of pain.

There have been several developments in regards to the legalization of cannabis in various other European countries, for example in Portugal. How are the processes looking there?

In Portugal, parliament is currently considering the legalization of cannabis for medical use. Although Portugal has one of the most liberal policies on drugs in Europe, they have still to decide whether to legalize medical cannabis.

Oddly enough, Portugal owns legal cannabis plantations since 2017, which grow the plant for export. The debate is even considering to allow patients to grow their own cannabis at home. This, however, is an issue that is still being discussed.

For scientist and doctors alike, the legalization of medical cannabis is not only seen as a way of alleviating patients'

pain and other symptoms, but also as a means to conduct more research into the topic.

## **How does Denmark's approach to the legalization of cannabis differ from the Portugal?**

As of January 1st, 2018, Denmark has initiated a four-year medical cannabis pilot program. It's guidelines are laid out in the act of medical cannabis pilot program, which allows companies to apply for admission of cannabis products at the Danish Medicines Agency.

Products that have been accepted by the Danish Medicines Agency are free to be legally prescribed by doctors and distributed by pharmacies within Denmark.

To date, scientific research into the effects of medical cannabis has been restricted by the law. With the start of the medical cannabis pilot program, Denmark is encouraging research projects in order to gather more science-based information about the use and effect of cannabis for medical use. For this purpose, the Danish government has allocated a DKK 5 million fund.

Unlike Germany, Denmark does not reimburse patients, who take medical cannabis unless all other possible medical products have failed them. This may affect patients with indications, such as multiple sclerosis, spinal cord damage, cancer patients undergoing chemotherapy and patients suffering from severe chronic pain.

## **In Italy cannabis has been legalized for medical use for a while, how does their legalization process look?**

The Italian Ministry of Health has been coordinating and monitoring the legalization process for medical cannabis. Since November 2015, it has had the power to distribute cultivation, production, possession and use permits.

In Italy, only licensed farmers are allowed to cultivate cannabis and deliver it to the Ministry of Health. The ministry then allocates the plant for production of an active substance, which is then bought by pharmacists. These, in turn, produce magistral preparations, which can be prescribed by doctors. Also, doctors have to specify which genetic strain is to be used by the patient, as well as the amount and consumption method: vaporizing or the infusion in hot water.

For medical purposes, cannabis in Italy is to be prescribed as a secondary treatment, which supports standard treatments for a number of indications: chronic pain, cancer, HIV, AIDS, glaucoma, spasticity and Tourette syndrome.

## **Let's take a look across the pond. How are legalization processes looking in America?**

During its legislative period, the Obama Administration issued a policy that discouraged federal prosecutors from pursuing cannabis-related criminal cases in states, which legalized the use of cannabis either for medicinal purposes or casual use. In California, for example, cannabis was recently liberalized for casual use.

However, recently the attorney general of Trump's Administration, Jeff Sessions, dismissed the Obama Administration's policy. This means that the non-interference of the federal government does no longer exist and the federal prosecutors could interfere with the states' decisions of the legalization of cannabis.

This has triggered looming, open questions in the US: What does this actually mean? What are the legalization processes now? For companies manufacturing, processing and distributing cannabis this has left a lot of uncertainty, as well as for users.

## **What impact will the widespread legalization of cannabis for medical use have in Europe and globally?**

What we will definitely see are more and more clinically trials. This will set out to observe and prove the effects of cannabis on various indications. We will soon know what indications it can be used for, where it makes sense.

Of course, there are certain publications already, but the fact that the use of cannabis for medical purposes has been illegal in most countries, has made the execution of scientific clinical trials basically impossible. This will soon change.

## Your Key Contacts



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