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SHEDDING LIGHT ON MEDICAL CANNABIS

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The medical cannabis industry is growing rapidly in Europe and thousands of patients are already prescribed with cannabis-based drugs. This created a new demand that now runs the risk of being unsatisfied if the legislation remains fragmented amongst EU countries.

Several decision-makers and stakeholders are calling on the European Commission to investigate which kind of regulatory measures at the EU level should be put in place to meet patients' needs.

Standards, safety, ethics and sustainability are the topics to discuss further when it will be time to draft guidelines and pieces of regulation with the aim of creating a regulatory environment for patients and investors.

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MEP: EU framework on medical cannabis to give 'peace of mind' to patients

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By Gerardo Fortuna | EURACTIV.com



"This is not alternative medicine. Medical cannabis should be considered a mainstream drug," said Maltese MEP Miriam Dalli. [CUGNOT/EP]

A strong EU regulatory framework on medical cannabis is needed to provide investors with stability but also to give peace of mind to patients struggling with fragmented legislation among member states, socialist MEP Miriam Dalli has told EURACTIV.

From patients' perspective, getting access to medical cannabis in the EU is not an easy feat, she pointed out in an interview held on the sidelines of the MedCann World Forum, which took place in her home country Malta from 19 to 21 November.

"We are speaking about medical,

not recreational cannabis," she said, adding that the therapeutical treatment with cannabis and cannabinoids seem still to be treated with too much of a precautionary attitude, as though patients were

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using them capriciously.

According to her, it is unacceptable that patients who regularly purchase medical cannabis in their home country should be in the situation where they are not allowed to take their medicine with them if travelling abroad within the EU, or even don't have access to it.

"If we really have our patients' well-being at heart, we need to make sure that they can access medical cannabis across the EU," she said.

Dalli called for a strong regulatory framework within the EU, citing the case of Malta as a trendsetter in laying down robust rules and regulations in the medical cannabis sector that have ensured quality products for patients and a quality market for investors.

In April 2018, Malta enacted the Production of Cannabis for Medicinal and Research Purposes Act, which provided a regulatory framework allowing business entities to cultivate, import, process and produce cannabis intended for medical and research purposes in a controlled and supervised environment.

"Our Mediterranean island is working hard to keep up the momentum and reap the benefits of the latest advancements," she said.

A number of other European countries are developing or have already put in place policies for granting patients easier access to medical marijuana after Germany led the way by passing a reform of the country's drugs law in 2017.

WEEDING OUT MISCONCEPTIONS

Dalli considered herself a 'firm believer' in simplifying matters and not complicating access to medicinal products that can have therapeutic effects.

"Processes that create a lot of obstacles and hurdles will not help

patients and will let the black-market fester. It's not what we want," she said.

As more countries will seek to tap into a growing market, the EU framework should ensure high-quality products for the patients. "Effective legislation does not hinder quality and it does not hinder growth," she added.

However, prescriptions of medical marijuana have not seen the expected boom so far in countries like the UK, where cannabis-based pharmaceuticals were re-classified as products that may be prescribed eight months ago.

Some medical doctors, in particular, seem reluctant to write prescriptions for medical cannabis because of a lack of clinical trials.

But according to Dalli, research alone should not be used as an excuse to restrict the use of medical cannabis when there is already enough evidence showing that the medication can help out a certain cohort of patients.

"This is a new area of science and professionals, maybe trained 10 or 20 years ago, were not used to prescribing cannabis," she said, adding that education for professionals is key.

For the Maltese MEP, helping medical doctors understand the research, the dosing and the endocannabinoid system can set the ball rolling, but the general view of medical cannabis needs to be changed.

"This is not alternative medicine. Medical cannabis should be considered a mainstream drug. After all, it has been used for a very, very long time," she pointed out.

CBD CONFUSION

In February 2019, the European Parliament adopted a resolution calling on the European Commission and national authorities to provide a legal definition of medical cannabis.

MEPs, in particular, intended to draw a clear distinction between medicines approved by the European Medicines Agency (EMA) or other

regulatory agencies, medical cannabis not supported by clinical trials and other applications.

On the research side, they also asked the Commission to determine the priority area of analysis, as well as embark on more research activity to stimulate innovation with regard to projects related to the use of cannabis for medical purposes.

Dalli wants to avoid medical cannabis suffering from the same confusion that previously surrounded food supplements containing the cannabis compound cannabidiol (CBD), which the Commission eventually decided to regulate as novel foods in January.

The novel foods distinction is for products that haven't been significantly consumed before 1997, but according to Dalli, this means CBD products need a time-consuming process to be registered as they need additional safety research.

"So far, few member states have enforced the European Commission's novel foods policy and some associations are challenging the EU's position," she said.

She also recalled that the World Health Organisation has officially recommended that the cannabis compound cannabidiol (CBD) should not be classified as a controlled substance.

EU should adopt German standards on medical cannabis, campaigners say

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By Gerardo Fortuna | EURACTIV.com



Medical cannabis cultivation in Portugal.
[TILRAY]

Germany's regulatory approach to medical cannabis is good practice and should be replicated across Europe, according to newly-born European Medicinal Cannabis Association (EUMCA).

The recently established lobby group is taking its first steps in the Brussels bubble, advocating for an EU-wide regulatory framework on medical marijuana.

While the market for medical cannabis is already well developed in some EU member states, only EU-wide standards can ensure patients have the same across Europe.

Different legislation across EU countries on prescribing cannabis-based medicines can hinder patients' access to their treatment when they travel abroad, EUMCA said.

"Our main priority is informing national and EU institutions about

the opportunity that this treatment is offering," said Sita Schubert, secretary general of EUMCA.

Lack of clinical trials is a major reason why doctors are cautious about the drug. But according to Schubert, health actors and lawmakers are also often simply not familiar with medical marijuana.

"The use of cannabis for medical

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purposes was forbidden for so many years due to strong national laws on narcotics that there was no opportunity of gaining experience with cannabis," she told EURACTIV.

GERMAN MODEL

But Schubert believes the positive example of Germany can change perceptions when discussing an EU regulatory framework for medical cannabis.

According to her, the German regulatory approach allowed developing a quality and safe market for cannabis-based medical products in the country.

In January 2017, the German Parliament passed a reform of the country's drug law, allowing easier access to cannabis products for therapeutic purposes.

Before the law was changed, only 1,000 patients were prescribed with medical cannabis. In 2018, after the law was passed, doctors issued approximately 142,000 prescriptions for medical marijuana only.

The national cannabis association Deutscher Hanfverband (DHFV) estimates that there are 50-60,000 health insurance patients prescribed with medical marijuana, which makes Germany the third-largest market for these products outside North America.

Following Germany's example, a number of other European countries developed policies granting patients easier access to medical cannabis.

The Czech Republic, Italy, Malta, the Netherlands and the United Kingdom are among the other member states which have established a specific access scheme for cannabis preparations for the treatment of a narrow range of medical conditions.

ACCESS AND QUALITY

As a growing number of patients were prescribed with cannabis-based drugs, the industry's revenues spiked as well. In Germany, statutory health insurance providers reported revenues of roughly €70 million for medical products containing cannabis in 2018.

But in the absence of an EU-wide framework, there could be growing unmet demand across Europe, EUMCA argues, saying the drugs can be not only life-changing but sometimes also life-saving.

In the past 20 years, there has been a surge of patient interest in using cannabinoids to treat a variety of conditions, according to the EU Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Those include chronic and cancer pain, depression, anxiety disorders, sleep disturbances and neurological disorders.

Marijuana is also used to treat glaucoma, while some patients with Parkinson's disease experienced lessen tremors, but more clinical trials are needed in this regard.

Patients without access to legal medical cannabis may, in the end, supply themselves on the black market, where no regulator can oversee quality or safety standards, EUMCA warns.

Licensed medical products receive the EU Good manufacturing practice (GMP) certification, a set of standards that all drug manufacturers must comply with.

The European Medicines Agency (EMA) coordinates inspections to verify compliance with GMP standards regarding the quality of drugs and whether they're appropriate for their intended use.

Before hitting the market, all medical cannabis sold in Europe needs to be produced and tested

under European GMP, together with Good distribution practices (GDP) certification for warehousing and distribution.

OPEN DOOR

EUMCA is willing to work with companies of all sizes to push medical cannabis at the EU level.

The German pharma association Bundesverband der Pharmazeutischen Industrie (BPI), which represent more than 250 companies is a member of the association, together with big companies in the sector such as Tilray, Panaxia and Materia ventures. But there is also room for smaller companies like Cannaflos.

"It is very important that companies speak with one ethical voice for medical cannabis," Schubert said.

"The future of medical cannabis is written now and it would be great if everybody who has an ethical medical approach would join us," she said.

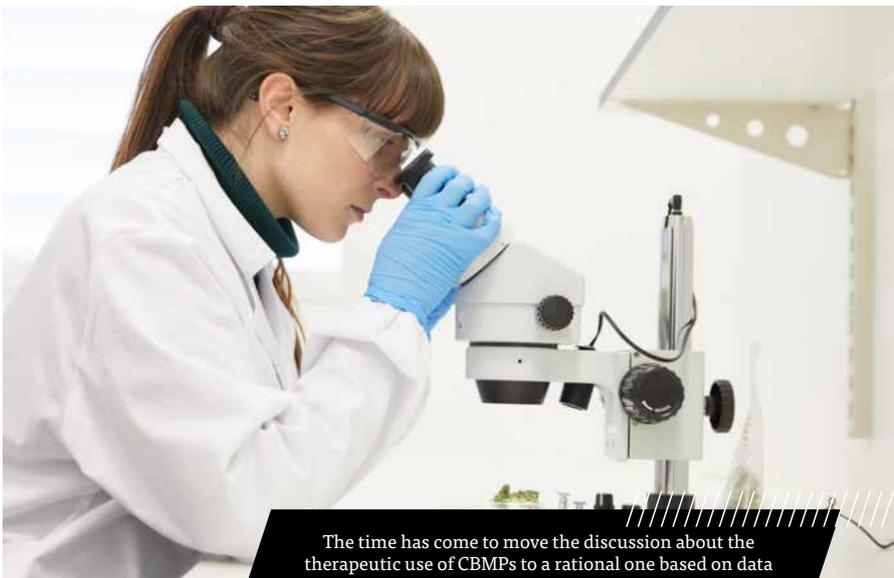
OPINION / PROMOTED CONTENT

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Governments are legalizing medical cannabis. Why is it so hard for patients to access?

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By Catherine Jacobson | Tilray



The time has come to move the discussion about the therapeutic use of CBMPs to a rational one based on data and common sense. [Photo provided by Tilray]

a pharmacy willing to receive the medicine, find a licensed importer willing to apply to the Home Office for an import permit, and submit the import permit to our company, Tilray. We would then apply for an export permit and expedite the shipping to a pharmacy for dispensing. At best, it would take 3 months.

Sadly, the lengthy process took more time than her husband had. He died four months later, without having had the chance to try a medicine that might have reduced pain in his last months. More than a year after legalization in the UK, millions of patients still face the same arduous path to access. Similar burdensome processes exist in the majority of the 41 other countries that have legalized medical cannabis in some form.

This problem is largely the result of legal access being granted before CBMPs are put through the traditional drug approval process, which is overseen by health regulatory agencies. In many countries, politicians have acted on intense demand from patients, moving quickly through legislation to legalize medical cannabis. In others, courts have ruled

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Patients deserve faster access to safe medical cannabis. Legalization is not enough – governments and businesses need to work together to reduce barriers and lessen patients’ reliance on the illicit market.

Catherine Jacobson is Vice President, Regulatory & Medical Affairs at Tilray.

Not long after medical cannabis was legalized in the UK last year, a woman from Northern England approached me to ask how she could

obtain a cannabis-based medicinal product (CBMP) for her husband with terminal pancreatic cancer.

He was in tremendous pain and traditional pain medications had not worked. He wanted to try a CBMP to find out if it might alleviate some of his suffering – the therapeutic potential of CBMPs for pain has been well documented – and she asked how she might gain access to the medicines.

I explained the process to her: find a specialist willing to prescribe the CBMP, submit that prescription to the regulator for approval, locate

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access to medical cannabis as a patient right. Regulations have struggled to keep up.

There is no precedence for providing access to a medicine without first receiving approval from a country's health regulatory agency. This has resulted in confusion at every level: doctors, patients, regulators, policymakers, and the public. So much misinformation is circulated on all fronts that it can be hard to tease out the critical issues, the evidence from which to make informed decisions about this complex topic and, most importantly, how to generate the right evidence to guide policy and regulations.

The therapeutic potential of CBMPs has been well documented, though a discussion about the level of evidence that should be required for specific medical conditions is still necessary. Multiple studies by leading scientists around the world have shown that CBMPs are generally safe or safer than other drugs approved for conditions such as pain and epilepsy. For any drug that is being prescribed, the doctor goes through an individual risk/benefit analysis for the patient. In the case of CBMPs, while the specific benefits may still be under debate, the risks are comparatively low.

Yet, regulations and standards set by the medical community are failing patients. This year, Tatterton & Walker¹ reported that over 87% of respondents from children's hospices in the UK know that their patients are receiving illicit cannabis preparations but cannot provide legal CBMPs. According to a survey conducted by the UK's largest medical cannabis advocacy organization, United Patients Alliance, 72% of patients turn to the illicit market for a product to treat their symptoms. A recent YouGov Poll estimates that 1.4 million people in the UK alone may be obtaining cannabis through illicit means to treat

medical conditions.

This estimate is not surprising given the hurdles of access to legal, pharmaceutical cannabis products via prescription in the UK. Not only does obtaining illicit cannabis from drug dealers pose safety risks to patients, they also don't receive the medical supervision they need and deserve.

There are solutions. We need to build a new cannabis-specific approach that safely serves patients while mitigating the risks to public health. Industry, government, and healthcare professionals all have a role to play.

Companies must continue to ensure doctor and patient confidence. This could be done by ensuring that their medicines meet pharmaceutical-grade global product quality standards based on guidelines set by the leading standard-setting body for medicines, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) or are manufactured under Good Manufacturing Practices (GMP).

Regulators must develop medical regimes that get CBMPs to patients in a time frame that matters and allow doctors the flexibility to prescribe the medicines. Creating a new process that speeds up approvals for CBMPs while working with the industry to develop real time patient registries to generate data on treatment, effectiveness, problems, and cost, will be critical.

A new regulatory approach is needed for several reasons. First, CBMPs do not contain novel chemical entities; rather, they are composed of the generic active ingredients, Cannabidiol (CBD) and Tetrahydrocannabinol (THC), that have been therapeutically used by humans for millennia. Second, cannabis-based medicine is personalized; not only does individual tolerability vary greatly, but the data to inform definitive clinical trials on a specific dose of a specific drug product

for a specific indication does not yet exist. And finally, requiring costly and lengthy clinical trials – and placing the burden of the investment squarely on industry – will result in significant price increases. This reduces the likelihood that the drug would achieve cost coverage by the national health insurance agencies and increases the probability that patients will continue to turn to the illicit market.

Finally, we all need to work together to better understand and address public health concerns about less restricted access to CBMPs, such as recreational use in youth, impaired driving, and addiction potential. These should be driven by reliable and robust data collection programs. We also need to make a clear distinction between therapeutic use of CBMPs and adult (recreational) use of cannabis. While the global debate on ending prohibition continues, it should not come at the expense of patients suffering today.

The time has come to move the discussion about the therapeutic use of CBMPs from one steeped in historical stigma around cannabis to a rational one based on data and common sense.

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PROMOTED CONTENT / VIDEOS

The European Medical Cannabis Association – the Brussels-based industry body – calls for harmonised EU regulatory framework to create equal access for patients

By Gerardo Fortuna and Michael Ball | EURACTIV.com



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medications. They are a global leader in cannabis research, cultivation, processing, and distribution and aspire to lead, legitimise and define the future of the medical cannabis industry by building the world's most trusted cannabis company, and to increase patient access.

Learn more about the EUMCA by visiting their site: <https://www.eumca.org/>

Learn more about Tilray: <https://www.tilray.com/>

The European Medicinal Cannabis Association (EUMCA), the newly formed Brussels-based industry body, represents the interests of ethical companies working in the supply and manufacturer of medicinal cannabis.

Incorporated on 14th November 2019, the EUMCA advocates for European evidence-based policy to improve patient access to high-quality cannabis treatment. Its aim is

to create a supportive and harmonised EU regulatory environment in which producers and manufacturers sign up to good manufacturing practices (GMP) and deliver medicinal cannabinoid treatments that conform with acknowledged scientific standards of quality, safety and efficacy.

An example of this is Tilray, a producer of medical cannabis treatments, and the first GMP-certified company to develop such



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