

Marketing Medical Cannabis in Europe

Major global cannabis exporters cannot tap into a common regulatory pathway to European markets. Cannabis is a massive opportunity, but marketing cannabis products in the diverse European market is a complex challenge, writes Arriello Director of Drug Safety Peter Kohut.

Medical cannabis has shown efficacy in trials and is being deployed legally in medical settings as a therapeutic for conditions ranging from palliative care for cancer to appetite stimulant in patients with AIDS-related wasting syndrome. Yet, there is considerable variation in regulatory approach between European countries.

Across Europe, some countries allow the use of medicinal products containing cannabinoids, while others allow the medical use of unauthorised products or preparations. Some have standalone medical cannabis programmes. Some countries allow cannabis product manufacture. Others do not allow manufacture but do permit cannabis import, while in other countries you can do both.

Even the definition of ‘medical cannabis’ is not fully agreed and terminology has grey areas. CBD is a chemical substance found in cannabis that has medical benefits. It is the key ingredient of approved medical cannabis drugs for children and adults with a rare form of epilepsy. CBD oils and supplements are also offered to consumers over the counter, but the efficacy of weaker consumer preparations is unproven.

Cannabidiol (CBD) is one of 113 identified cannabinoids in cannabis plants and accounts for up to 40% of the plant’s extract. Clinical research on CBD includes studies related to anxiety, cognition, movement disorders, and pain. CBD does not have the same psychoactivity as THC, the primary ingredient in cannabis that “gets you high”.

Tackling the Challenge

There is a pressing need to have clear policies and regulations and harmonisation across territories. Until that happens,

European markets present a challenge. The first step in tackling that challenge is recognising that European countries fall into three broad groups when it comes to their legal framework for medical cannabis. Some countries, including the UK, the Netherlands, Poland and Portugal, have well-established medical cannabis legislation.

In many of these countries, the relevant legislation is quite recent. The government of Greece approved the legalisation of cannabis for medical use as recently as 2018, the same year as the UK, while Germany made it legal for doctors to prescribe medical cannabis in 2017.

Cyprus is governed by the Medical Cannabis Law 2019, which states: “Patients will be supplied with medicinal cannabis by pharmacies upon presentation of a prescription from a specialist physician. This process ensures that patients will receive quality cannabis, under the supervision of a specialist, avoiding the need to obtain cannabis of dubious quality from the illegal market.”

In these countries, the use of medical cannabis is clearly provided for under law and pharmacovigilance regulations relating to medical cannabis are the same as for medicinal products. That means patient safety is the same as for any other drug and the same measures can be taken to identify and deal with counterfeit drugs.

In other countries, including Sweden, Latvia, Belgium and Albania, medical cannabis is strictly prohibited. It is illegal to use, buy or sell cannabis. At the present time, there are no routes to market medical cannabis into those countries.

Somewhere in the middle are countries that permit the supply of specific cannabis products under specific conditions. These include countries with trial period or pilots underway examining the possibilities for the use of medical cannabis. In these countries there are opportunities to market medical cannabis, with care.

Some countries allow importation and/or use of medical cannabis at the discretion

of physicians, usually relating to specific treatment for a named patient. In Croatia, for example, there is just one cannabis medicinal product registered containing cannabidiol (Epidyolex). The only way to register cannabis there is through an imported licence.

France, Ireland and Denmark are running trial periods for medical cannabis, while in Finland only Sativex (an oromucosal spray) is available on prescription, for patients with MS. CBD may be prescribed for other conditions, decided on a case-by-case basis by the Finnish Medicines Agency (FIMEA). A prescription can only be issued by a neurological expert (or doctors in a neurological clinic) and is viewed as a ‘last resort’ if the patient hasn’t responded to other medication.

Narcotics Licences

While some countries have specific regulations relating to medical cannabis, in others, products that contain cannabinoids that do not have any formal authorisation as medicinal products, may have a narcotics licence, as they do in Germany, for example. Similar narcotics legislations in other countries may provide life sciences companies with a route into these markets.

Clearing the Hurdles

In European countries that do allow medical cannabis, whether in established law or in pilot projects, there is a further issue relating to the form of preparation allowed. Medical cannabis may be supplied in oils, capsules, as dried plants or a liquid solution. On top of that, there is a lack of standardisation in the manufacturing of medical cannabis products, their ingredients and labelling.

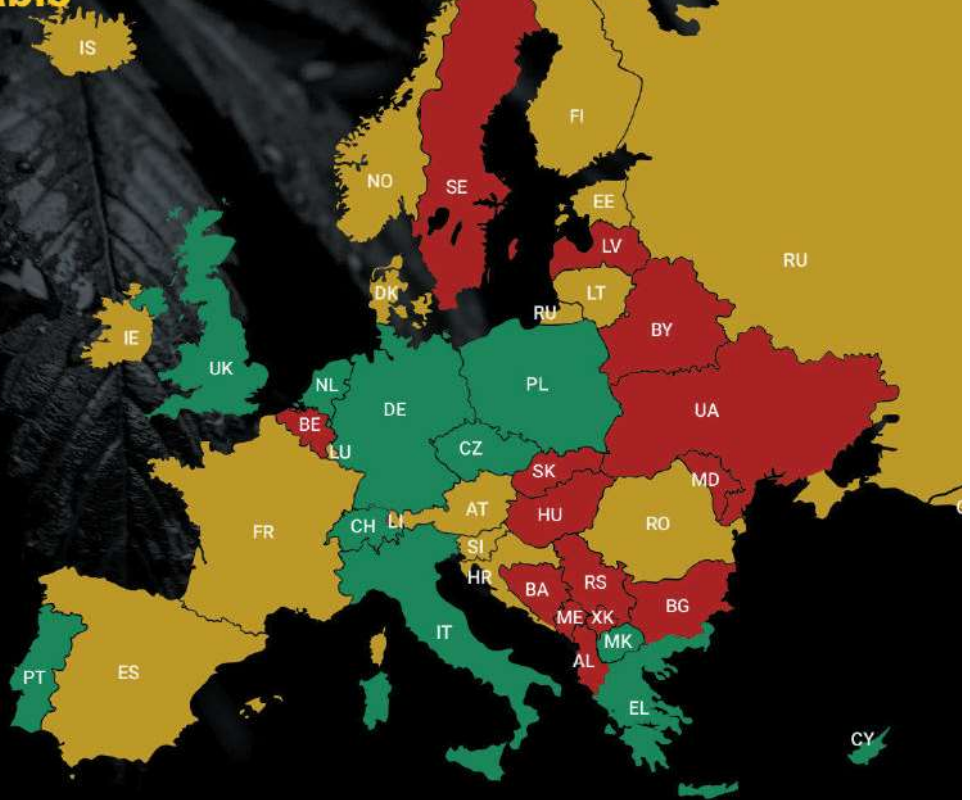
There are further questions about how to get medical cannabis into the hands of patients. In target countries, is access to medical cannabis products prescription-based or is OTC provision likely for some formulations? Will prescriptions be limited or not? Will prescriptions be reimbursed by the government or insurance companies? The answers to these questions are all key to building a business case for marketing medical cannabis into individual territories.

Legal framework of medical cannabis in Europe:

12 Countries with well-established medical cannabis legislation.

16 Countries that permit the supply of specific cannabis products under specific conditions / Countries with test/trial/pilot period for use.

15 Strictly prohibited. It is illegal to use, buy or sell cannabis in these countries – not in the scope of this guide.



There is little consistency across Europe relating to when medical cannabis may be used as medicinal products – and for which patient conditions. Clinical trials are showing good results for many conditions but there is only Europe-wide approval

for one medicinal cannabis product. The European Medicines Agency granted Orphan designation to UK-based GW Pharma for Epidiolex (cannabidiol) for the treatment of Dravet syndrome, and Lennox-Gastaut syndrome, rare and severe forms of epilepsy.

The European medical cannabis market is complex. But this complexity is not a barrier to entry to a market that is becoming increasingly attractive to major pharma players. Now is the time to grasp the nettle and get ahead of the competition.



Peter Kohut

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