

Exploring the CBD opportunity

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by Heather Granato

The COVID-19 pandemic has wreaked havoc around the globe, separating families, plunging nations into economic distress, and exacerbating underlying health issues. It's no wonder that consumers are reporting higher levels of insomnia, stress and anxiety; it's probably also no wonder that interest has accelerated in cannabidiol (CBD). Research from Prohibition Partners released in October 2020 suggests 28% of CBD users have been in the market for less than six months.¹ Further, 52% of consumers are using CBD to help with sleep and relaxation, while 51% use it to manage health and wellness and other health conditions.

Drawing consumer interest

In fact, health and wellness support is a major driver, according to David Foreman, known as The Herbal Pharmacist. "Consumers are interested in addressing key areas of health—pain, sleep and stress—in which modern medicine offers options with significant side effects," he commented. "Additionally, there has been such a 'buzz' in

the media about CBD and it being legal that many have sought it to be the next, latest, greatest supplement."

That assessment was shared by Najla Guthrie, president and CEO of KGK Science. "Globally, consumers are showing similar trends in their shift towards alternatives to pharmaceuticals for self-care health products," she said. She cited a recent report published by Health Canada that found 93% of respondents were interested in HC-approved cannabis products as a natural alternative to pharmaceuticals.

Beyond the positioning as a natural alternative to mainstream treatments, CBD ticks several boxes. "It sits at the intersection of a number of broader consumer trends including natural/plant-based medicines, environmental sustainability, functional ingredients, no/low alcohol drinks and a push for general wellness," said Tom McDonald, head of consulting, Hanway Associates.



Potential for Europe

Whatever the reason, CBD is trending globally, driven by mature markets in the United States and Canada. However, there is great opportunity in the European market, according to a new report from New Frontier Data.² It expects annual spending on CBD in the EU to total an estimated €8.3 billion (mid-range estimate) for 2020, and is projected to grow at a CAGR of 10.4% to reach €13.6 billion by 2025.

The report states: “The market remains immature given that only slightly more than half (56%) of Europeans surveyed have heard of CBD, compared to nearly nine-in-ten (86%) of US respondents. This underscores the wide awareness gap that still needs to be closed. Further, as consumers become more aware of CBD, the likelihood of finding relevant applications to their own lives increased due to the wide range of ways in which CBD is used. Closing the familiarity gap will therefore be a key step in driving new consumer adoption and increase the frequency of use among consumers who may be using CBD intermittently for a narrow range of reasons.”

While the regulatory situation is still unsettled, growth is up across most territories, said Freddie Dawson, head of content, CBD-Intel, with some positive category growth; however, he added, the lack of a settled European regulatory outlook is hampering large-scale entry by major brands. “We have seen the entrance of Nestlé (through a subsidiary and with minimal

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fanfare), which is impressive, though it should be noted that Nestlé is a Swiss-based company and the expansion is in the UK—the European country with the most settled, and most friendly, CBD regulations,” he observed. “That is also the reason why Amazon elected to start its trial there—which insiders say is expected to be made permanent and expanded before the end of the year. Other companies have dabbled or have said they’re poised to enter as soon as regulations permit.”

The UK is one of the most dynamic CBD markets, with New Frontier Data projecting €1.71 billion in annual spending on CBD in 2020, exceeded only by Germany at €1.83 billion. The firm expects both markets to grow by more than €1 billion apiece by 2025, to €3.01 billion in Germany and €2.80 billion in the UK.

Nicole Brown, chief commercial officer at Open Book Extracts, commented on the growth to date in these markets, as well as potential geos to watch. “In Germany, CBD-only products have thrived both in and outside of typical cannabis channels; individuals can get a prescription through the state medical program, or they can buy CBD through mainstream channels such as smoke shops, online, and natural food stores,” she said. “In the UK, CBD has gained traction in recent years as an alternative in a market where access to medical cannabis is tightly restricted. CBD has gained distribution through large retailers such as Holland & Barrett, Superdrug, and Tesco, bringing CBD products to a wide range of consumers.



Switzerland has taken a more liberal approach to CBD than much of the continent, allowing CBD products to be sold as consumer products and is sold in over 1,000 tobacco shops. CBD is also widely available through grocery outlets, cosmetic stores, and CBD specialty stores. And Austria has a large and growing demand for CBD. While edible and cosmetic CBD products are currently banned, CBD oils may still be sold as 'aromatherapy products' and smokable hemp is available in a wide range of outlets including grocery stores, CBD specialty stores, and even vending machines."

Evolution in delivery

Product formats are quickly evolving across Europe. Dawson noted topicals are quite widely accepted across the EU, with sports-specific and joint support topicals available, and a trend around topicals to address issues that may have an inflammatory aspect, such as psoriasis. Beyond the topicals, he commented, "Currently there is a lot of experimentation, with companies

attempting many different things and seeing what works, rather than creating a narrow plan and focusing on that."

Of course, he continued, there are considerable questions for companies that are experimenting. "Adding CBD to foods, drinks and dietary supplements remains at best legally ambiguous and really technically illegal under most regulatory regimes," Dawson said. "Beyond that, there remain serious challenges to integrating CBD into beverages—including

shelf life, stability, degradation, taste and interaction with packaging. Many of those challenges also apply to other formats, with CBD easily degraded by exposure to sunlight among other factors."

Bioavailability and dosage

It is therefore no wonder there are continued questions about delivering CBD appropriately and in efficacious doses. The question of bioavailability has dogged the market for years. "Bioavailability of orally-ingested CBD is very low so products such as drinks, capsules or gummies need to have significant volumes of CBD in them to have any meaningful physiological effect," McDonald said. "Many companies are now looking to novel 'nano' formulations that have been shown to increase bioavailability; but, in Europe, any foods that include nano technology will also be subject to Novel Food regulations, so companies may face significant delays before these products move out of the 'grey' market."

Dawson observed there are a range of ways that companies are using to increase bioavailability, including nanoparticulation, but also micro-encapsulation, micelles and emulsion. However, Guthrie commented, "Bioavailability and pharmacokinetics need to be established in healthy people for products with different formulations and routes of administration, which will have a substantial impact on metabolism."

TINY Technologies GmbH is a contract development and manufacturing organisation that investigates the application of drug-delivery technologies to nutraceuticals. Its CEO, Thorge Debus, shared that the company is collaborating with the University of Hamburg Department of Technical Chemistry to develop different patented technologies for CBD formulation, as well as other fat-soluble actives. He commented, "This is the most important step to bridge the gap from expensive and



generic CBD products to highly efficacious and cost-effective remedies."

Similarly, Brown observed: "CBD is poised to be a major disruptive force across a number of markets, particularly in health, wellness, and nutrition. New ingredient technologies that optimize CBD delivery in food & beverage applications are going to be a key part of this transition." OBX partnered with and collaborated with Prinova to develop a collection of patented water-soluble CBD ingredients under the Hydrobond CBD™ brand. By utilising fully traceable, high purity CBD from OBX, and leveraging Prinova's patent-pending manufacturing process, the result is a water-soluble, broad-spectrum distillate; the ingredient can therefore be more easily formulated into powder and liquid food and beverage applications.

Backed by science

While consumers are seeking CBD to support their health in areas such as sleep, stress and inflammation, and formulators are finding ways to go beyond a traditional extract or tablet, there remains the question of scientific research on the efficacy of CBD.

"Clinical research substantiating the health effects of CBD is critical," Guthrie emphasised. "Regulatory authorities in Europe and North America require competent and reliable scientific evidence to support health and structure/function claims. Many products are marketed to healthy individuals but there is very limited data in these populations. CBD has vast potential in the health and wellness space but there are many research gaps and

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the science needs to catch up to the quickly moving CBD market." She added that KGK Sciences is expecting to receive a Canadian license soon that allow the company to conduct human clinical trials and sensory testing for CBD products.

Harm Hids, head of product development and business development, Europe, Medcolcanna, noted that there has been a great deal of research done showing positive effects of CBD, but the question is taking those results to a spot where a company could both

monetise and make claims. "This is where we are stuck," he observed. "Not in the lack of positive research."

Similar thinking was put forward by McDonald, who noted Hanway sees two distinct paths emerging for CBD and other cannabinoids. The first could be a pharmaceutical route, whereby clinical trials are conducted to yield a 'medicine' marketed as a drug; Epidiolex would be an example, with substantiation for use in a limited number of disease states. However, given the cost of this path, McDonald expects to see most CBD companies focused on the ingredient for general wellness. "This does limit the claims that brands can make but will allow them dramatically lower R&D costs that can be passed on to consumers," he commented. "A number of our clients are also running small consumer-focused trials that will allow them to make 'soft', non-medical claims over their CBD wellness products similar to those seen with other



health supplements sold in-store and online without a prescription."

Regardless of the pathway, developing and conducting well-designed trials is a key aspect. "Not all studies are created equal and they should not be treated as such," Dawson said. "There remains a deal of skepticism in mainstream scientific circles about the use of RWE (real world evidence) and real-world data (RWD) in the place of traditional double-blind clinical trials. The relative merits of a properly designed RWE/D trial versus a clinical trial are still hotly debated. There also remains some skepticism of industry-sponsored research. It begs the question of who would do it if the industry did not pay for it, but not everyone approves of research funded by those that stand to gain from positive outcomes. That is something to keep in mind when discussing the slowness of regulatory implementation by food/drug safety agencies."



The big question mark

The regulatory question is perhaps the biggest one on the minds of suppliers and marketers. There have been some recent decisions related to CBD's status in Europe that offer possibilities for the future. For example, the November Kanavape ruling declared that France's national ban on marketing hemp-derived CBD products violated EU law on the free movement of goods within the bloc. CBD is covered by the

EU's free movement provision, the judges said, because [CBD derived from the entire hemp plant] is not a narcotic under the 'purpose and general spirit' of the Single Convention on Narcotic Drugs (1961).

Further, at the start of December, the UN Commission on Narcotic Drugs voted on six recommendations to change the scheduling of cannabis and related substances in two international treaties, including the one cited in the French ruling. However, only the recommendation to make cannabis a Schedule I and not Schedule IV drug was passed; the recommendation that could have added a footnote to the 1961 convention setting a 0.2% limit for "predominantly" CBD preparations failed by a significant vote.

Reporting from Hemp Industry Daily suggested it was less the principle of liberalisation of CBD, but the verbiage of the recommendation that scuttled passage. Monica Raymunt reported: "Delegates for several nations, including the United States and Germany on behalf of the European Union, cited the proposal's unclear wording and its departure from drug treaty norms when explaining their dissenting votes but signaled a willingness to revisit the issue. The recommendation represented a missed opportunity to clarify the confusing legal situation for CBD preparations with traces of THC, but commentaries from CND members indicated that the proposal was drafted in an ambiguous way, and the WHO's responses to member states' questions about the recommendation over the past two years had created additional confusion."³

McDonald expects further opening of the European market once both decisions are reviewed, particularly as they may affect the European Commission's decision on whether to review CBD products for novel food status. But for now, he stated, "Regulations regarding CBD are set at an EU-level but different interpretations and enforcements at

a country-level have led to a patchwork of different barriers and opportunities. This has led to different product formulations and formats being legal in different countries."

What it means for developers

This poses considerable challenges to the future of the CBD industry in Europe. Guthrie commented: "In order for the market to thrive and compete with North American industry, some level of legal harmonisation is required across member countries. This means clear and consistent directive from the EC as to the legal status of CBD and whether its trade between member states under the Freedom of Movement of Goods rules is permitted. It means establishing a

recommended marketplace on the EU level so that member countries can align their respective laws and determine the sales channels through



which CBD can be sold. Guidance pertaining to the safe levels to be included in various product forms and uses should be issued from the EU to help facilitate harmonisation as well. Establishing the guideposts required for a responsible industry and a safe consumer is critical. However, it must also be recognised that the industry consists primarily of small to medium businesses and the pre-market investment required for entry may be prohibitive should safety requirements not be specifically tailored to the unique situation that CBD poses, given the current widespread consumer access in a grey-market. Existing infrastructure for dietary supplements and

herbal medicines should be leveraged but facilitating access starts with defining the market and legal sales channels."

The future is green

Even with the regulatory uncertainty, efficacy considerations and formulation challenges, consumer interest is still on the rise. "One of the most surprising things about CBD is the breadth of people who are using it," McDonald said. "We have seen everyone from anxious millennials to arthritic OAPs building CBD into their daily regimes. The key to succeeding in this busy sector is identifying exactly which consumer segment you are aiming to please and tailoring your product format, formulation, branding and marketing efforts to best serve these individuals." One path forward, he suggested, was for companies to use CBD in combination with other substantiated ingredients for targeted health issues or demographic groups.

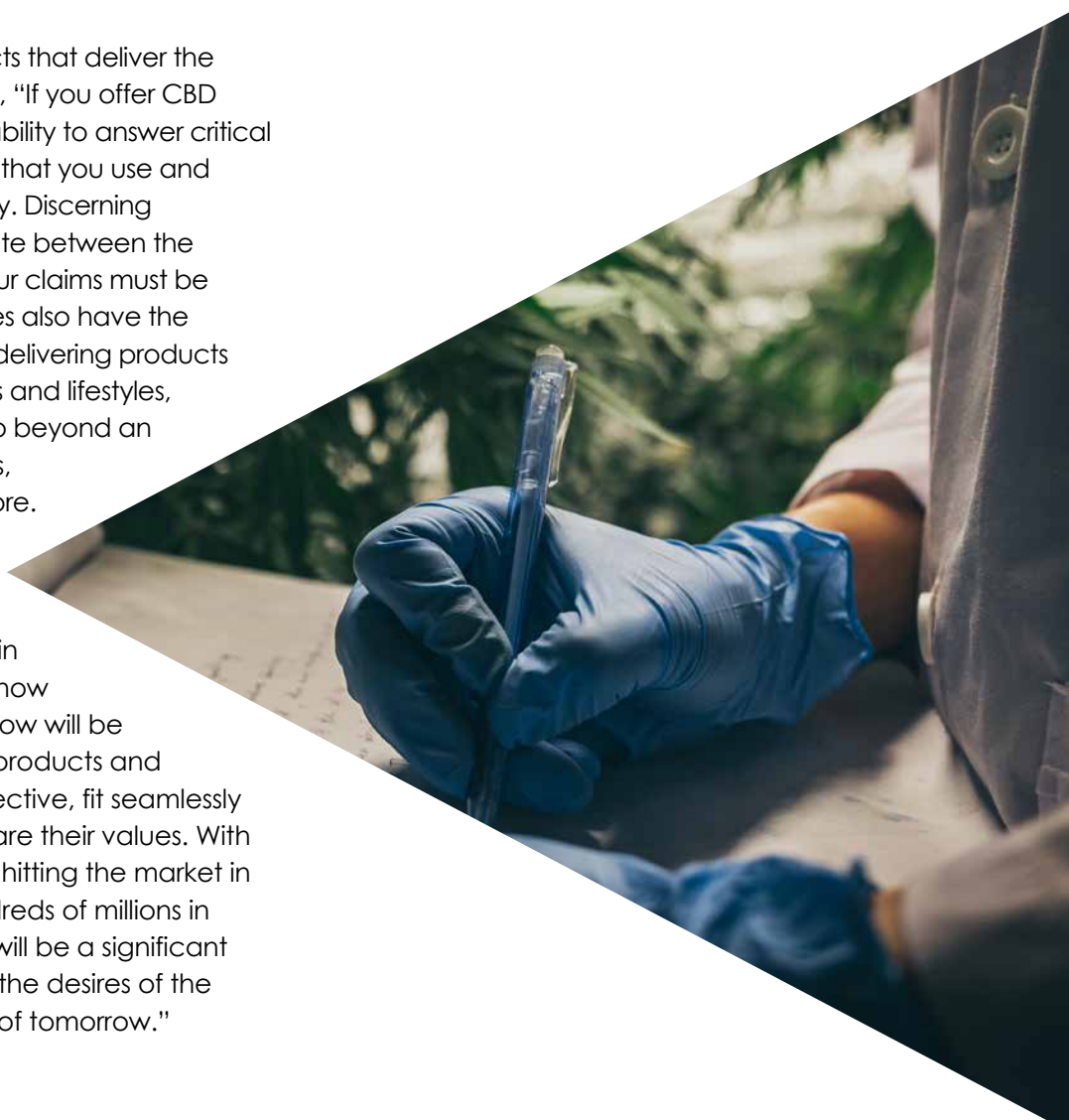
Dawson stated the CBD sector has expanded beyond the 'Gwyneth Paltrow' type of initial target market, "urban, cool, aware of the importance of issues like mental health, with the cash to pamper themselves." Instead, he continued, "that has expanded to take in other demographics—professional and amateur sports people, the ageing, a younger generation less into alcohol and more into recreational/relaxation use of cannabis. More than likely, there remains significantly more work that could be done in convincing ageing and elderly generations of the benefits of CBD. Many will not like the cannabis aspects that permeated early CBD brands and branding. However, there are enough brands that have moved ahead sufficiently from such connotations that if awareness of the issues that CBD could potentially address was raised, then there would likely be room for expanded sales."

The path forward, Brown said, will come down to three areas—efficacy, quality and form. For the first two, consumers are turning to CBD to address health issues, and are seeking



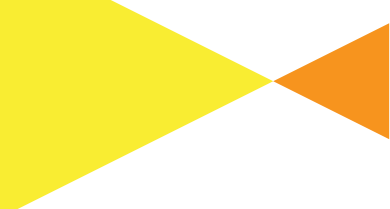
premium wellness products that deliver the desired effect. She noted, "If you offer CBD products, you need the ability to answer critical questions about the CBD that you use and again, articulate its quality. Discerning customers can differentiate between the quality of products, so your claims must be accurate." But companies also have the opportunity to innovate, delivering products that meet different needs and lifestyles, allowing formulators to go beyond an extract and into gummies, beverages and much more.

Brown concluded: "If we look at the modern CPG marketplace, especially in the US and Europe, we know that the buyers of tomorrow will be most interested in novel products and brands that are safe, effective, fit seamlessly into their lifestyle, and share their values. With hundreds of CBD brands hitting the market in Europe, backed by hundreds of millions in funding, we know there will be a significant investment into meeting the desires of the sophisticated customers of tomorrow."



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Biographies

NICOLE BROWN, CHIEF COMMERCIAL OFFICER, OPEN BOOK EXTRACTS

Nicole Brown serves as chief commercial officer for Open Book Extracts (OBX), responsible for overseeing the successful direction, planning, and execution of the OBX commercial strategy to drive business growth and market share, inclusive of sales, strategic partnerships, product development, marketing, and customer service. Prior to joining OBX, she served as senior director of global business development for TripAdvisor, which grew from the acquisition of Citymaps, where she was CMO. Previously, she held management roles at LVMH and Shiseido Cosmetics, driving global commercial success through excellence in branding, product development, consumer engagement, and immersive experiences.

FREDDIE DAWSON, HEAD OF CONTENT, CBD-INTEL

Freddie Dawson is head of content at CBD-Intel, the global CBD information and news service run by Tamarind Media, focusing on market and regulatory developments. Freddie was formerly a business news journalist for CBD-Intel and its sister service ECigIntelligence.

THORGE DEBUS, CEO, TINY TECHNOLOGIES GMBH

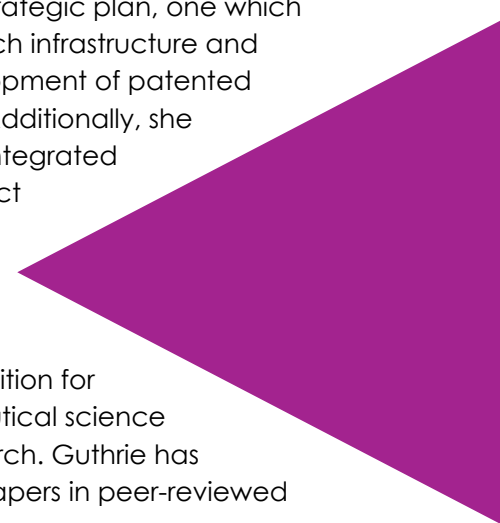
Thorge Debus has long been engaged in topics related to cannabinoids, terpenes and pharmacological active ingredients. Prior to founding TINY Technologies, he acquired extensive know-how in this exciting industry as Entrepreneur in Residence. TINY Technologies GmbH is a contract development and manufacturing organization based in Hamburg, Germany which uses drug-delivery technologies to create dynamic products for the nutraceutical and pharmaceutical industry.

DAVID J. FOREMAN, RPH

David J. Foreman is a pharmacist, author and media personality known internationally as 'The Herbal Pharmacist.' His background in both pharmacy and natural medicine put Foreman in an elite class of health experts who can teach integrative medicine practices. He is a frequent guest speaker at universities and international conferences around the globe, and provides R&D to help companies formulate scientifically substantiated and innovative nutraceuticals. Foreman is a graduate of the University of South Carolina College of Pharmacy and is author of hundreds of articles, journal articles and books.

NAJLA GUTHRIE, PRESIDENT & CEO, KGK SCIENCE

Najla Guthrie is the president and CEO of KGK Science; under her leadership, the company has successfully established and executed a novel strategic plan, one which leveraged its research infrastructure and financed the development of patented in-house products. Additionally, she has brought KGK's integrated research and product development team to a world-class level, with the group receiving international recognition for its efforts in nutraceutical science and cannabis research. Guthrie has published over 50 papers in peer-reviewed journals and has given numerous presentations at both the national and international levels.



Biographies

HARM HIDS, HEAD OF PRODUCT DEVELOPMENT & BUSINESS DEVELOPMENT, EUROPE, MEDCOLCANNA

Harm Hids' connection to medical cannabis came through a deeply personal journey. His son, who was suffering from Crohn's Disease, was no longer responding to traditional treatments. When he discovered the benefits of medical cannabis, he developed a formula that proved successful for his son. Tests on hundreds of other patients resulted in remarkable response rates. He then expanded his efforts into formulating medicines and food supplements for other diseases. Harm is fascinated with pharmacokinetics and discovering how to deliver cannabinoids to the right place, at the right time, in the right form.

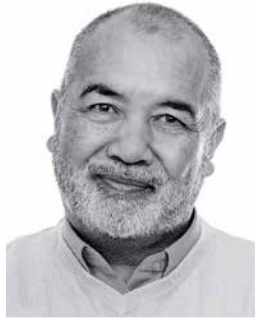
TOM MCDONALD, HEAD OF CONSULTING, HANWAY ASSOCIATES

Tom McDonald manages the Hanway Associates consulting practice which has been helping clients understand, operate and grow within the emerging European cannabis sector since 2017. This role has given him unique insight into the workings of many mainstream CBD and wellness companies alongside multinationals looking to enter the sector. Prior to this he consulted for a variety of top tier pharmaceutical companies at Accenture and IQVIA.





Q&A



Company Name: Swiss PharmaCan

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Title: Chief Marketing Officer

www.swisspharmacan.ch

1 How do you see the future of CBD ingredients and how does your innovation fit in that vision?

Most people don't realize how bad CBD oil is being absorbed. Tests have shown that at best 15-20%, but on average only 5-10% of the CBD oil we take orally is ultimately being absorbed. A staggering 80-95% of the CBD oil you take, your body will never use!

Swiss PharmaCan developed a technology that imitates the natural process our body uses to absorb fat, but then much more efficiently and effectively. CBD products created with this MyCell Technology are absorbed by the body almost instantly. The results? Increased absorption from 5-10% to up to 100%, resulting in stronger and faster effects. Often within minutes instead of hours, and without using any synthetic compounds like sorbates or glycerin.

MyCell Technology improves the absorption and effectiveness of not only CBD extracts, but also of ingredients like Turmeric, Vitamins, Coenzyme Q10,

Omega 3 and many more. MyCell Technology was awarded the prestigious CPhI Award for best formulations in 2018.

Besides MyCell enhanced CBD full spectrum, CBD distillate and CBD isolate, we can also supply MyCell enhanced minor cannabinoids, like CBN, CBC and CBG and a variety of mixes, like CBD with Curcuma.

Fast working, highly effective and 100% natural MyCell enhanced products are the future of CBD.

2 In what categories of products are your ingredients ideally suited for formulation?

MyCell Technology improves the absorption, protects against degrading by acid, and increases cellular uptake. More of the active ingredient will reach there where it is needed and it will do so faster.

Anywhere where a consumer prefers faster and better results, our MyCell enhanced products will outperform any non-micellized ingredients.

3 How do you define your company's point of differentiation and advantages in the market?

The majority of the market is still using CBD in oil, even though many tests have demonstrated the poor availability and stability of these products. Consumers are becoming more and more aware that they are throwing away up to 95% of the product they paid for and are quickly switching over to water-soluble alternatives. With them achieving the same results at a lower dosage, or (much) better results at the same dosage. Often far exceeding expectations.

There are more water-soluble products in the market, but the MyCell Technology is the only encapsulation system that is based on the same process our body uses, using only 100% natural components.

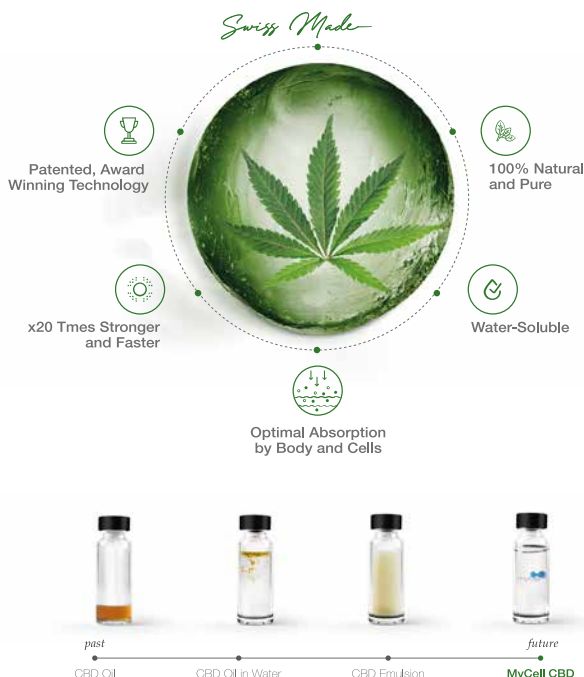
Made in Switzerland, using patented Swiss technology and pure natural ingredients, MyCell enhanced products outperform all other products.

4 What type of additional support do you offer your customers—formulation and R&D insights, regulatory guidance, consumer market data, etc.?

Swiss PharmaCan only sells under white and private label to other companies. For those companies that haven't yet got their own brand, we can assist them with creating a brand and with the regulatory issues. We also offer the possibility to assist with bottling, labelling and packing of our products.

We offer our customers the possibility to be different, to be better and to be part of the future, today. In a market that is flooded with almost identical products this is critical to be also successful tomorrow.

THE FUTURE OF CBD THE BEST MADE *even* BETTER





Empowering industry thinkers

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Vitafoods Insights is a community-powered knowledge platform designed to help the industry connect, develop and progress. Bringing together the best nutraceutical minds, we focus on the trends and market developments that matter. Championing knowledge with purpose, we publish content that drives better business solutions for industry professionals.

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