



# THE EUROPEAN MEDICAL CANNABIS MARKET INVESTMENT IN STRATEGY



KOMAND Consulting is a Toronto-based strategy and corporate finance advisory firm and a global leader on assisting companies enter the European medical cannabis market. Since 2006, KOMAND has been working with business leaders from public and private companies to identify their core competencies, critical challenges and capitalize on high-growth opportunities.

In 2015, KOMAND entered the cannabis sector to help companies develop their global growth strategies, pursue M&A and corporate development opportunities and access private capital.

Please visit [www.komand.ca](http://www.komand.ca) for more information.

# INTRODUCTION

Once in a generation, an opportunity arises to enter an industry that has yet to get off the ground. The fledgling takeoff of the global cannabis industry arouses memories of the advent of the internet in the 1990s, and if one were to open up the history books, there are several examples of new industries that grew rapidly to become multi-billion dollar within a short period of time. One such example is the 1930s post-prohibition transition from an enormous illegal trade in alcohol to the main street.

And so it has come to pass. The USA's combined recreational and medical cannabis market surpassed \$12bn in 2019, and Canada joined the billion dollar club in that same year (\$1.6bn). The accompanying excitement of capital markets culminated in the industry's first boom-bust cycle with an abrupt selloff in the second half of 2019, firmly resetting investor appetite for North America.

Now, the ever-enduring eye of capital is casting its gaze across the Atlantic to Europe, an embryonic market (<\$400m) with enormous potential. The consumer purchasing power and population alone of this \$18.3trn GDP economy is enough to warrant investment analysis. However, in the absence of a clear EU-wide cannabis market, supply chain and distribution model, investors can not fall back on conventional North American market benchmarks and valuations (themselves encapsulated by only a few years of data). Strategic thinking must be part of any investor's decision to enter the EU cannabis market and in this sense, a strategic investor e.g. licenced producer, and private investors' considerations are the same.

This primer charts the map of the European market (market sizes, supply routes, products etc.) before presenting simple strategic considerations for investors. KOMAND has developed a proprietary market forecasting model and a strategic plan evaluation tool for EU market entry (for different business types), which are incorporated into the

investment decision factors presented herein.

Generally, KOMAND has observed not just unrealistic widely-publicised market forecasts, but an enormous disparity in the strategic planning abilities of European cannabis companies' management teams. Any investor should be armed with at least a realistic expectation of the European market size, and a moderate understanding of the strategic choices to be made now, before engaging with an investment opportunity. This approach will save much pain in the near future, and reap long lasting rewards.



**Nasos Makriyiannis**

*Managing Partner*

KOMAND Consulting

*"As time goes on, I get more and more convinced that the right method of investment is to put fairly large sums into enterprises which one thinks one knows something about and in the management of which one thoroughly believes." - John Maynard Keynes*

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## **PAPER AT A GLANCE**

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Investors and operators alike have been misinformed in Europe and are now paying dearly. To rectify this, KOMAND runs through the most important considerations for the European market, and introduces a blueprint for identifying the best and worst positioned strategies.

### **MARKET CONDITIONS**

The European medical market is steadily growing while heavily regulated under existing pharmaceutical legislation. Products will slowly morph into more pharmaceutical forms. Participants need to understand the important European country specific details, as being misinformed is fatal and quickly so.

### **MARKET FORECASTING**

To date, European market forecasting has been overstated and unusable for business decision making. KOMAND illustrates its 2-level forecasting approach (Projections & Forecasts) and the importance of each in developing competitive go-to-market strategies.

### **INVESTMENT IN STRATEGY**

In a brand new industry, choosing a viable strategic position is imperative for success and initially, survival. KOMAND introduces its 6-Arch™ model for identifying the best strategies in a very European context. European outcomes will not mirror the successes and failures as seen in North America.

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# MARKET CONDITIONS

## In Bullets

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### European Market

- The entire European market is numerically at the level of Canada circa 2016
  - The total market is no bigger than €250m (2019)
  - Dried flower volumes are still under 10,000kg (2019)
- Product trends are towards extracts and isolates, and away from flower
- Pricing varies widely between countries and product categories
- Future product supply is from within the EU, for the EU market

### Medical Cannabis Products

- Magistral (galenic) preparations by pharmacies have a large market share
- Dried flower is beginning to see price compression
- Commoditization of full-spectrum extracts has big near-term potential
- Pharma-cannabis is the big money long term play, but requires more evidence

### Regulatory Framework

- Europe is a maze of country specific legislation and product pathways
- Any commercial opportunities rely on legislative viability intra & inter-country
- Don't enter the market unless you've prepared for this in minute detail

### Indications for Prescription

- New clinical evidence for indications will bring more market opportunities
- Current data shows 45yr+ average user age for European medical cannabis
- Gray market has increasing medical usage and informal evidence for cannabis

# MARKET CONDITIONS

The European medical cannabis market can be characterised in many ways; disparity, intrigue, much naivety, some competence and proficiency, and unmistakable opportunity. This opportunity is often publicised as a “sleeping-giant market of 700m people coupled with an \$18trn economy”, a definite mischaracterisation. More apt would be to describe it as a field of sleeping unicorns, where some will soon awake and bolt and others will remain in stasis for many years to come. The European Union still has an end goal of becoming the aforementioned giant, but achieving the necessary level of fiscal harmonisation (of a USA) is a reality far away, perhaps a dream that may never come true.

However, the European opportunity remains real and indeed huge, enabled in a large part thanks to progressive legislation and commercial integration since the Maastricht Treaty (1992). In fact, one clear advantage does exist over the USA; the permissible movement of medical cannabis intra-Europe. This has a profound effect on pan-regional business strategy and ultimately the way in which the medical cannabis industry will form and mature.

## EUROPEAN MARKET 2020

In its current form, the market is a smattering of cottage industries across 5 countries with Germany being the first market to push through the €100m sales barrier in a year. The total weight of dried flower being supplied for medical purposes is still below 10 tonnes (a crude market indicator). For context, the weight totals are approaching the sales of dried flower in

### **Exhibit 1 – EU medical cannabis markets - 2019**

EU Market 2019	Medical Legalised	Retail sales	Flower supplied	Prescriptions	Patients
 Germany	2017	€140m	6,728kg	267,348	50,000
 Italy	2013	€20m	861kg	26,042	12,998
 Netherlands	2003	€4.7m	580kg	48,500	11,000
 Denmark	2018	€7.0m	29.76kg	12,097	4,326
 Czech	2013	<€1.0m	17kg	4,145	2,000
 Florida	2016	US\$525m	51,948kg	460,469	291,865

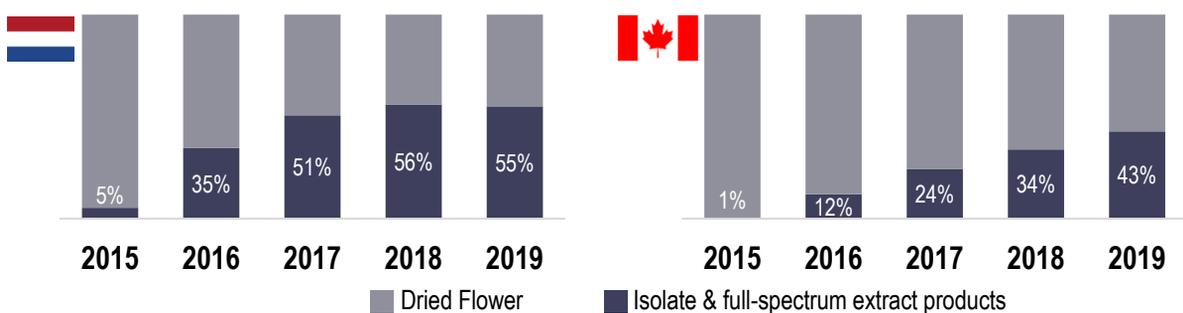
Source : National health authorities, National Drug agencies, National Cannabis agencies, KOMAND

Canada in the June 2015 to June 2016 period (11,473kg sold) when registered patient numbers climbed from 30,537 to 75,166 (June 2016).

### Medical Sales Moving Away From Dried Flower

Since that earlier period in Canada’s medical market, cannabis extract (oil) products increased annually as a percentage versus dried flower, a trend similar to that of another long standing medical market in Europe, the Netherlands (Exhibit 2). The Dutch Foundation for Pharmaceutical Statistics (SFK) attribute the rise in extract products to ease of use and less

**Exhibit 2 – Medical cannabis dispensations for Netherlands and Canada**

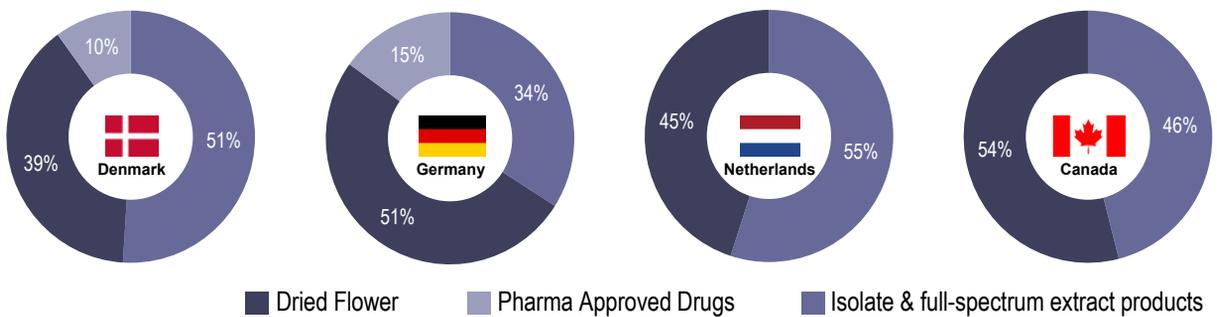


Source : Stichting Farmaceutische Kengetallen (SFK Netherlands), Statistics Canada

patient preparation requirement e.g. vaporisation of dried flower. Also, higher accuracy and consistency of the extract form has given Dutch doctors a viable alternative to the often maligned smoked-flower delivery. As a representative medical cannabis market, the Netherlands is insightful, as Dutch patients have access to a legal recreational alternative, with the ability to “self-medicate” in cannabis coffee shops. This fact helps purify the medical dispensation data to a certain extent as registered patients themselves are pointedly seeking guidance from doctors resulting in a prescription, rather than simple legal access to cannabis. Canada is beginning to see a similar “purification” trend in its medical market post recreational legalisation, with medical flower sales down by 22%, and oil sales up 25% (both by volume).

### New Medical Cannabis Markets in Europe

A “new wave” of medical cannabis legalisation in Europe has brought a fresh approach to the industry. All European legalised markets are strictly medical (thus far), and the EU medical cannabis market is a more focused pharmaceutical industry adhering to strict EU level

**Exhibit 3 – Percentage of prescriptions dispensed, by product type (latest reported quarter)**

Source : eSundhed, GKV-Spitzenverband, SFK Netherlands, Statistics Canada

pharmaceutical quality standards. New entrants must adapt to this, as succeeding in Europe requires adherence to higher clinical standards than in the US/Canada, and competition will soon arrive from the pharmaceutical behemoths i.e. Glaxo, Novartis, Bayer, Roche.

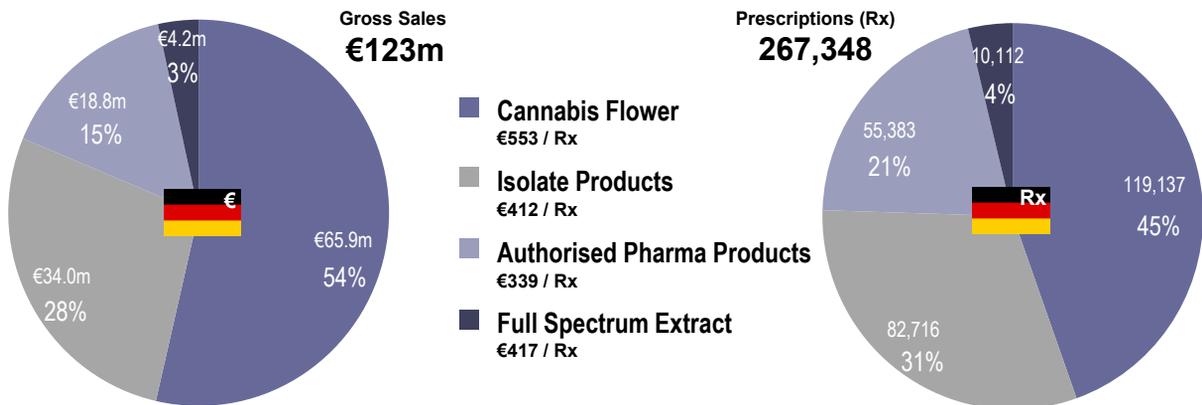
The new wave includes the EU member states Germany and Denmark (legalised in 2017 and 2018 respectively), having different looking medical markets relative to USA/Canada. Early on, the German and Danish dried flower prescriptions have already fallen to 50% (or less) of market share, with flower being used increasingly as an active pharmaceutical ingredient (API) for advanced, controllable and accurately dosed products prepared in liquid forms or capsules. The increasing evidence of medical cannabis's efficacy will continue to push the product form to more accurate and clinical forms, providing doctors with more alternatives to flower.

German and Danish dried flower prescriptions still do carry a “hidden recreational” subsegment, which has yet to undergo the Canadian “purification” process (from legalisation of recreational). Regardless, in 2 years German and Danish non-flower products have leapfrogged their way to prescription market shares that Netherlands and Canada took 5-7 years to reach (Exhibit 3).

### The German Market and THC pricing

Looking at Germany, Europe's de facto cannabis leader, 2019 saw the flagship catch wind with dried flower imports doubling (6,728kg vs 3,129kg in 2018) and retail turnover up 67% (€137m vs €82m in 2018) in the trailing 12-month period. Germany's National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) publishes quarterly prescription and retail sale totals broken down by medical cannabis product category (Exhibit 4). Across all medications,

**Exhibit 4 – Sales and prescriptions (insured) of medical cannabis in Germany for 2019**



Source : GKV-Spitzenverband

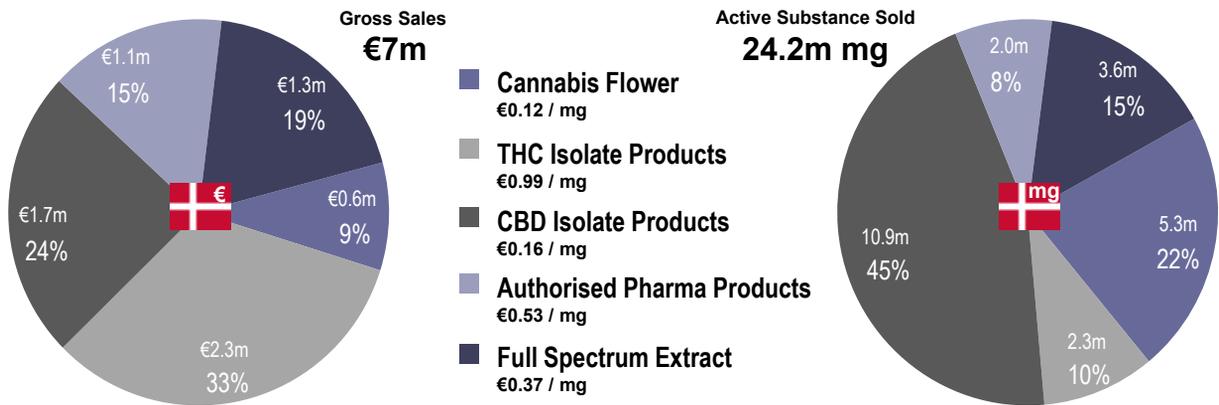
90% of Germans’ prescriptions are covered by this statutory health insurance, and since 2017 this coverage has been extended to medical cannabis, critical for market growth. On the prescription and sales numbers themselves, what is apparent are market premium prices paid for some product categories over others. In Exhibit 4, Isolate Products e.g. Dronabinol drops, Authorised Pharma Products e.g. Satviex and Full Spectrum Extracts e.g. Tilray THC 25 prescription cost (€/Rx) fall roughly in line with their retail price per package (see *Medical Cannabis Products* section), implying one package per prescription. Cannabis Flower, however, has an average of €553/Rx implying 28 grams per prescription (at €20 per gram, 2019 retail price) over multiple packages.

28 grams of high-THC dried flower delivers about 5,600 mg of pure THC to the patient, a vastly higher quantity than the other product forms for the same price. Therefore, on a per milligram (mg) basis, Isolate and Full Spectrum Extract products command 7-9 times the price/mg versus Cannabis Flower. All THC milligrams are created equal, but some milligrams are more equal than others.

### Cost per Milligram, the Denmark Standard

The Danish health authority (Sundhedsstyrelsen) has put this price/mg concept at the heart of their medical cannabis reporting, taking the novel approach of expressing sold quantities in milligrams across product categories, in order to have a universal basis for comparison. In Exhibit 5, the Danish market reveals in more detail the disparity in €/mg paid across categories.

**Exhibit 5 – Sales and milligrams of medical cannabis sold in Denmark for 2019**

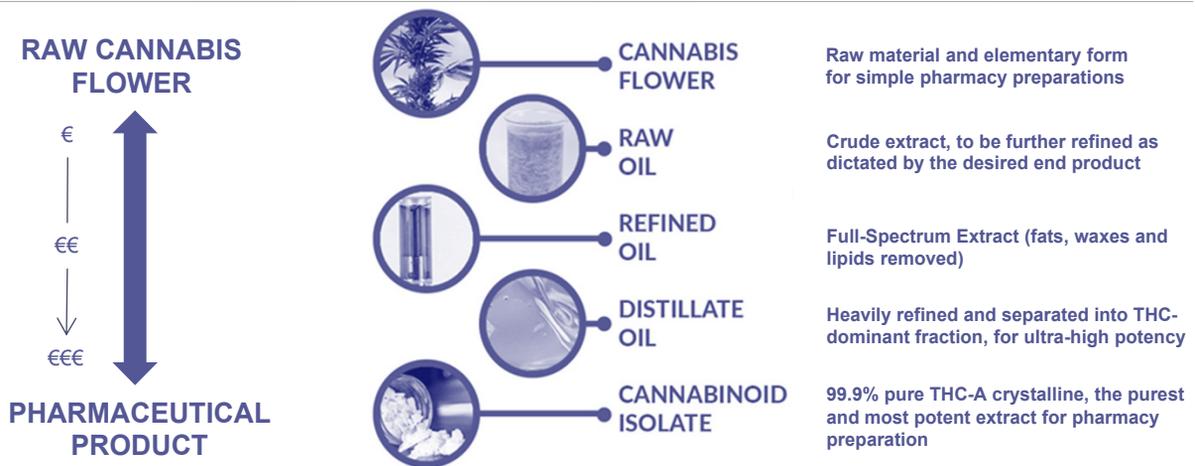


Source : eSundhed

For example, THC isolate products constitute 10% of the Danish market by quantities of mg sold, but 33% of revenues. On the other hand, CBD isolates and Cannabis Flower represent 67% of quantity, but only 33% of revenues.

*“All THC milligrams are created equal, but some milligrams are more equal than others”*

**Exhibit 6 – Range of Medical Cannabis products through the processing chain**



Reasons for the THC isolate milligrams commanding such a premium over others include;

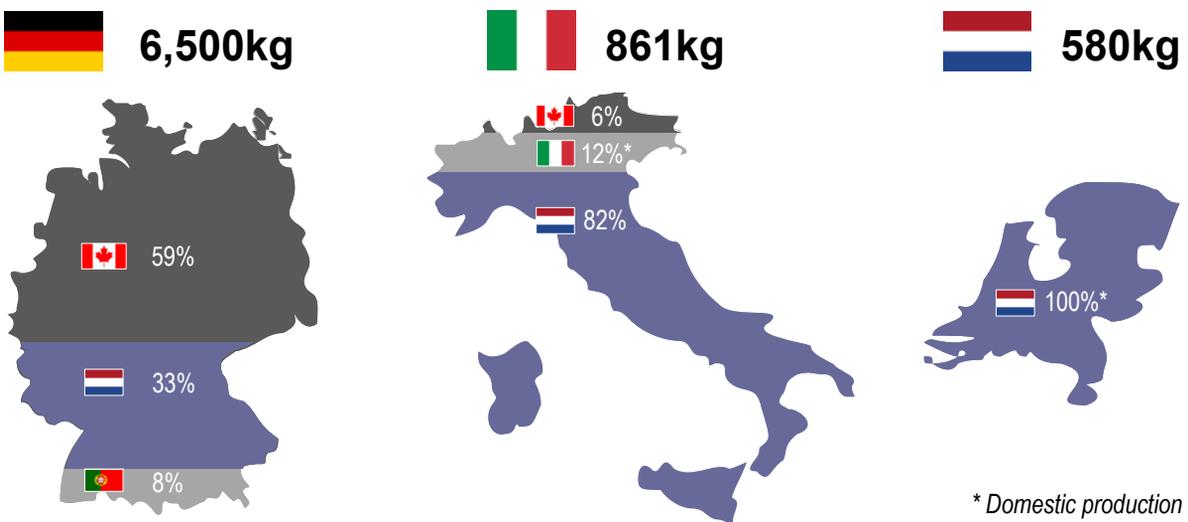
1. Higher concentrations can be dosed in this form
2. The cost of production is higher to get to the pharmaceutical form (see Exhibit 6)
3. The dosing is more accurate, consistency with a precision unattainable in full-spectrum oil

4. Full-Spectrum extract products (like Tilray THC 25 or Stenocare THC) are either in short supply or not available
5. Danish/German THC isolate is organically manufactured Dronabinol, delivering the same active ingredient as branded Marinol (Authorised Pharma Product - synthetic THC)
6. Dronabinol (THC isolate) is considered a cannabinoid pharmaceutical, with associated clinical data and testing to back up prescriptions by doctors (see *Medical Cannabis Products* section)
7. CBD is not classified as a narcotic, and is widely available as a consumer packaged good. There are lower barriers to entry for this product in isolate form

### European Raw Flower – Supply & Demand

Over 95% percent of European medical cannabis is consumed in Germany, Italy and the Netherlands. In 2019, the lions share of this was supplied by producers in Canada (49%) and the Netherlands (43%). This Canada/Netherlands dominance, however, is a temporary one. As the

**Exhibit 7 – Supply of dried flower (by country of origin) for distribution to pharmacies for 2019**



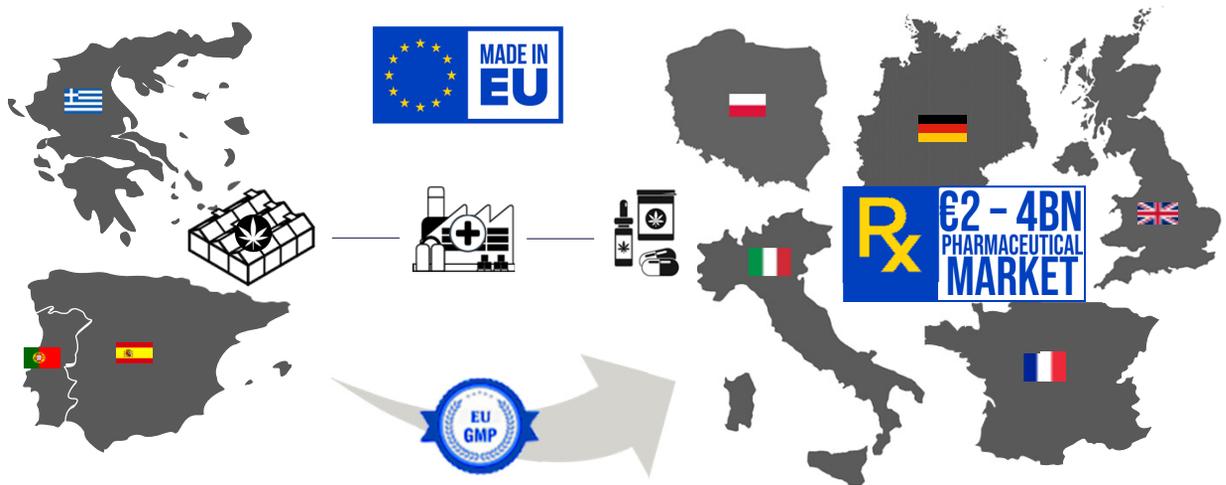
Source : OMC, Deutsche Bundestag, Ministero de Salute Italia

demand scales up, bulk flower and extract production from the Mediterranean region will prevail. Portugal, Spain and Greece have positioned as suppliers (Portugal and Spain are already shipping to Germany), prioritising an export orientated medical cannabis legislation. With their climatic advantages, and lower labour costs, these countries are able to produce at a lower cost per gram, while availing of intra-EU logistic advantages and high EU level pre-existing pharmaceutical production standards. In the long term, the “sourced in EU, manufactured in EU, for the EU” brand argument will carry weight in the THC product categories, as pharmaceutical buyers will

remain sensitive to consistency of quality and given the historic narcotic nature of medical cannabis. EU pharmaceutical production standards are recognised as more stringent than those of North America.

Importing from outside the EU does not make economic sense in the long run, especially as a handful of Mediterranean licenced producers should be able to supply the entire market. In the medium term, some northern European suppliers (Bedrocan, Demecan, Aphria) shall produce for an under supplied market, albeit at a higher cost of production.

**Exhibit 8 – The future of the European medical cannabis market - 2024**



Source : KOMAND

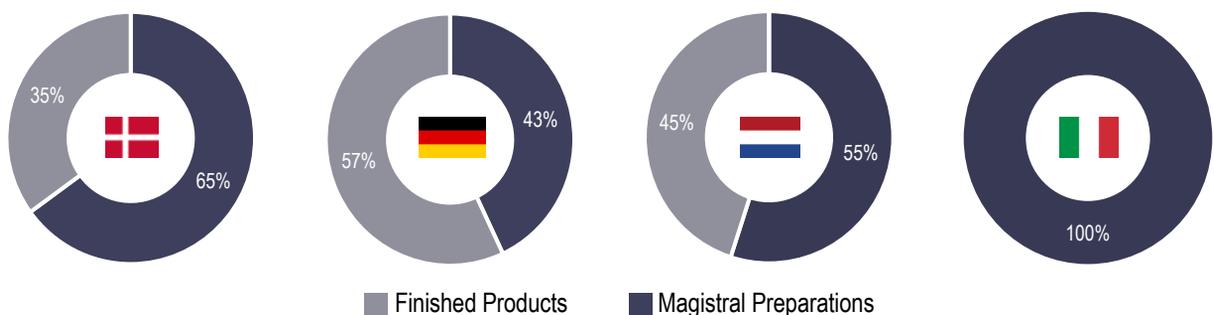
## MEDICAL CANNABIS PRODUCTS

The European market comprises of 4 key product types; Dried Flower, Full-spectrum products, Isolate products, and Authorised Pharmaceutical products. We chose the German and Danish market products to showcase these categories, as they serve as good proxy markets for Europe, with a relatively deep product makeup, at least 2 years of pilot program prescription activity and regular reporting of prescription data. But firstly, some consideration should be given to magistral preparations and their role in the European market.

### Magistral Preparations

Finished product medical cannabis is plant-based, manufactured by a company as a standard preparation and authorised under European countries' pilot/special medical cannabis schemes. However, magistral preparations are products manufactured in the dispensing pharmacy and manufactured specifically for the individual patient based on their prescription. There are a myriad of these magistral preparation products concocted by specialized pharmacists across Europe, using raw cannabis flower or dronabinol (manufactured by C3 Ethics GmbH, owned by Canopy Growth) as the active pharmaceutical ingredients (APIs). Magistral preparation scalability is limited to the pharmacy-by-pharmacy labour process to fulfill these orders.

**Exhibit 9 – Magistral preparations vs finished products prescription count**



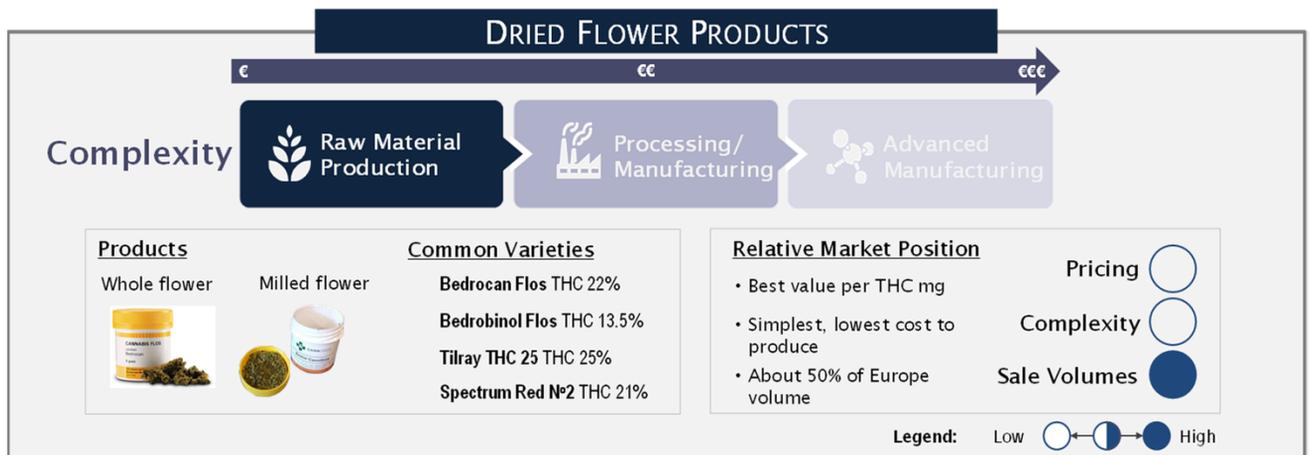
Source : eSundhed, GKV-Spitzenverband, SFK Netherlands, Italian Ministry of Health

For now, this value-add activity plays a major role in the market, and commoditisation has some way to go. As an extreme example, Italy (Europe’s 2<sup>nd</sup> largest market) has mandated that all medical cannabis must be sold as magistral preparations (Exhibit 9), with the entire dried flower market playing an API role e.g. an input for tea/vaporisation preparations, full-spectrum extracts, tinctures and others. If the patient has been prescribed dried flower itself, the pharmacy is

obliged to take the flower out of its original packaging, and place it in a pharmacy-branded bag as a magistral preparation. In Germany and Denmark, dried flower and full-spectrum oils are commoditised in practice. Dronabinol is the main API used in magistral preparations. Finally, in the Netherlands, Full-Spectrum extracts are the main magistral preparation (prepared in three Dutch pharmacies, named on Bedrocan’s website).

**Dried Flower Products**

Dried flower products are the talk-of-the-town in the early-stage European market, and the easiest for the general public to understand and identify with. Early attempts at establishing a brand are underway in this category, with first-mover medical cannabis names i.e. Bedrocan, Spectrum, Aurora, Aphria vying for the consciousness of the prescribing doctors and a presence on the shelves in pharmacies in Germany and Denmark. Although retail prices (>€20/gram) of these products currently support high margins, it is generally accepted that price compression is imminent as European produced supply begins to fall on the market. For the dried flower product, the tactical objective now is to boost volume, establish trade pathways, distribution networks and relationships and build brand awareness.



Bedrocan (Netherlands based) has the strongest medical flower brand presence in Europe, and they have the highest number of established pathways and sales channels to the various markets. Canadian brands are hot on their heels, with others to follow in the foreseeable future.

*“price compression (dried flower) is imminent as more European cultivated supply falls onto the market”*

### Full-Spectrum Extract Products

The Full-Spectrum extract products represent a big step-up in prices and margins versus the dried flower products. Although the extract sale volumes in Germany and Denmark are 15% or less of the market, they make up more than 50% of sales in the Netherlands and Italy, countries with a much higher reliance on prescribed magistral preparations (in Denmark and Germany they are sold as finished products). Doctors are more amenable to the extract administration mode and ease of dosage compared with dried flower. For example, smoked flower doses have



inconsistent therapeutic effects (loss of potency from combustion) and patients themselves must learn how to prepare the product e.g. vaporiser with prescribed consistency. The extract administration mode (sublingual) has the cannabinoids metabolized through the stomach and then the liver, taking longer for the effects to appear than when inhaled, but having a much longer (and often stronger) therapeutic effect on the patient.

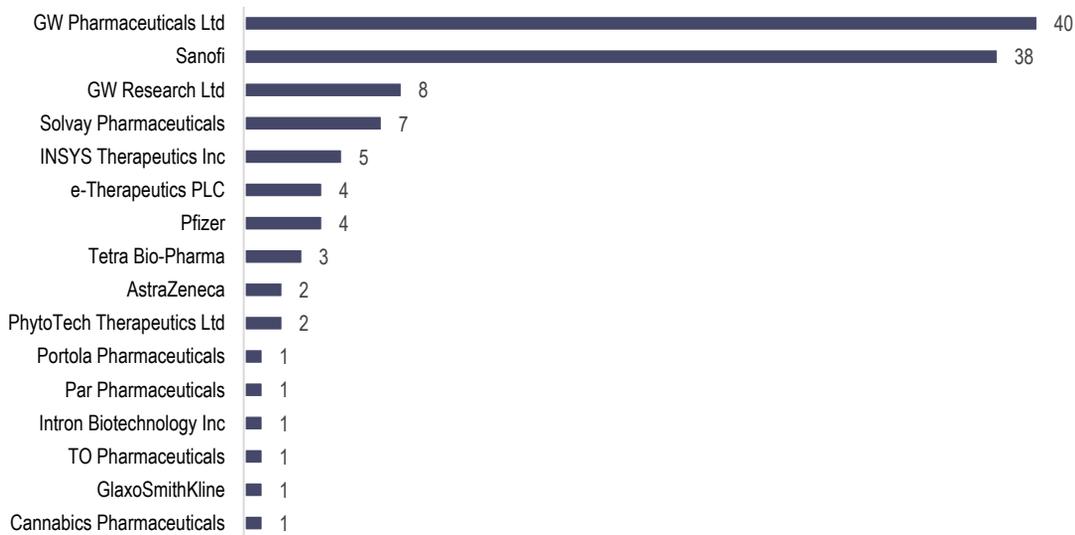
Full-Spectrum extracts preserve the terpenes and flavonoids of the plant, resulting in a taste similar to the plant and favourable to many incumbent dried flower cannabis users (versus isolate products). The often lauded “entourage effect” dictates that the cannabinoids, terpenes and flavonoids in the extract work together synergistically to augment the therapeutic application of the THC cannabinoid, frequently cited as an advantage over isolates.

Brand-wise, Tilray is the predominant (commoditised) participant in Europe, being the main seller in Germany. Stenocare’s extracts sold well in Denmark (in 2019), but had to be pulled in September as Canntrust (Canada) had been the manufacturer (the product was illegally grown).





**Exhibit 10 – Number of medical cannabis clinical trials registered with the FDA (by company)**



Source : Cannabis Business Executive, Jan 2019

There is an ongoing effort to drive medical cannabis into the conventional pharma product stream. Active clinical studies are in progress (Exhibit 10), and the time to validation of efficacy found within the clinical trials will be the delay to mainstream commercialization. In the wake of the opioid crisis, cannabinoid based drugs’ potential for pain management has led some experts to recommend them as an alternative to the addictive painkillers. Hence, the stage has been set and the gauntlet laid to the medical cannabis industry to come up with a sufficiently enticing and accepted line of products.

Many European countries, having an active medical cannabis program, allow access to an array of medical products (all aforementioned products in this section) without the clinical trial data needed to substantiate these products’ claims for mainstreaming in the healthcare industry. Any pharma-approved drugs e.g. Epidiolex have a major advantage over such cannabis products, having received the coveted approval. In addition to a lack of efficacy data, a critical barrier to the current testing of medical cannabis is the ability to maintain consistency from batch to batch during the production process. These higher production requirements may continue to present

*“one of the biggest barriers to the current testing of medical cannabis is in the production process’s inability to maintain consistency from batch to batch”*

a major hurdle for small medical cannabis producers whose products are currently derived solely from a botanical source, with mega-resourced pharma companies sitting on the sidelines ready to pounce the moment any commercial viability emerges.

To conclude, the medical cannabis that we know today will not be the medical cannabis we know tomorrow. The real future of medical cannabis will not be in the form of botanical products, but rather in cannabis-derived medicine that is focused on isolated, molecular compounds which allow for consistent and standardized delivery mechanisms that mirror traditional pharmaceuticals.

## REGULATORY FRAMEWORK

The regulatory framework in Europe consists of 2 key elements, namely national legislation and product pathways. Legislation creates the end points of the pathways, but a pathway must have a bilaterally agreed process e.g. import/export process between two countries in place to allow product movement. The European market is purely medical, ensuring that much of the legislation is derived from pre-existing pharmaceutical and narcotic laws, characteristically restrictive and setting a high bar for the many required approvals needed for manufacturing and transport. However, one clear advantage of the European medical cannabis market over the US (temporarily at least) is that medical cannabis products can be moved cross-border between nations. Europe is far behind the US's medical cannabis sales, but this advantage enables a fresh approach to the nascent market, and a different scope for strategic planning is merited.

Nation	Year Legal	Status	Flower/Oil	Dronabinol	Sativex	Insurance	Cultivation	Distribution	Export
Germany	2017	EU leading domestic market, commencing cultivation	✓	✓	✓	Yes	Yes 3 licences	Yes	Yes
Netherlands	2003	BMC has issued a tender for 2 new cultivation licences	✓	✗	✓	No	Yes 1 licence	Yes	Yes
U.K.	2018	Domestic market & cultivation moving very slowly	✓	✗	✓	No	Yes	Yes	Yes GW Pharma
Italy	2013	Strict pricing controls, Bedrocan only viable foreign supplier (80%)	✓	✗	✓	Yes	Yes 1 licence	Yes	No
Poland	2017	Restrictive, but flower sales have commenced	✓	✗	✓	No	No	Yes	No
Czech	2013	90% Insurance coverage approved in Jan 2020	✓	✗	✓	Yes	Yes 1 licence	Yes	Yes
Denmark	2018	Open and transparent, looking to export to EU	✓	✓	✓	Yes	Yes 44 licences	Yes	Yes
Austria	2008	Restrictive for the time being, no sign of pilot or easement	✗	✓	✓	No	Yes 1 licence	No	No
Switzerland	2011	Restrictive, A pilot program should commence this year	✓	✓	✓	No	Yes	No	Yes
Spain	2005	No domestic market, 1 cultivator now exporting to Europe	✗	✓	✓	Yes	Yes 1 licence	No	Yes
Portugal	2018	No domestic market, 1 cultivator now exporting to Europe	✗	✗	✓	No	Yes 5 licences	No	Yes
Greece	2018	No domestic market, purpose set up for cultivation/export	✗	✗	✗	No	Yes 29 licences	No	Yes
France	2013	A pilot program should commence this year (Sept 2020)	✗	✓	✓	No	No	No	No
Norway	2016	Restrictive for the time being, no sign of pilot or easement	✓	✗	✓	No	No	No	No

Source : KOMAND

### German Legislation and Pathways

Taking the most developed medical cannabis market, Germany, the legislation allows for multiple commercial pathways. Permitted activities include medical cannabis import, warehousing of imported products, the manufacture of more advanced products, the distribution of products to pharmacy chains, the further export of warehoused products to other markets and (more recently) domestic cultivation. All stated activities have different commercial viabilities, depending on the current legislation and permissible pathways (some are dependent on the import/export counterparty). On top of all that, a most critical trigger is the provision of public insurance for medical cannabis prescriptions (Germany has had this since 2018). Domestic medical markets cannot achieve critical mass without this.

**Exhibit 11 – German Legislation & Pathway (Regulatory Framework) examples**

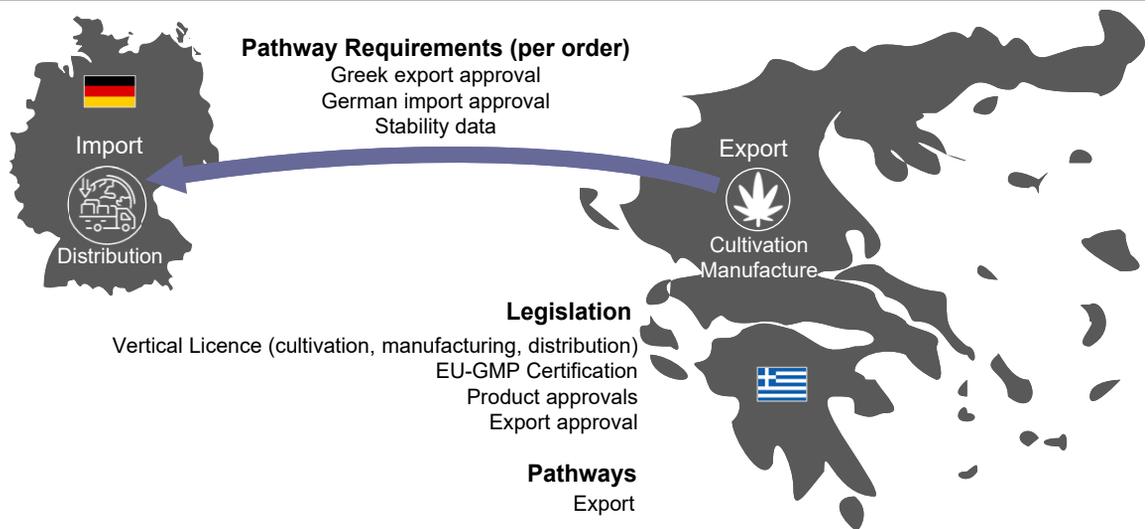
 <b>Example Medical Cannabis business types</b>			
	<b>Import &amp; Distribution</b>	<b>Manufacturing</b>	<b>Cultivation</b>
<b>Legislation</b>	 <p>Licence for import Licence for wholesaling Licence to trade narcotics Irradiation permit</p>	 <p>Licence to manufacture EU-GMP Certification Licence to trade narcotics</p>	 <p>Licence for cultivation EU-GMP Certification Product approvals</p>
<b>Pathways</b>	<p>Import from Canada/Netherlands Distribute to pharmacies</p>	<p>Sell to domestic pharmacies Export to European Importers</p>	<p>Sell to BfArM</p>

German licenced importers must import from a foreign EU-GMP pharmaceutical grade cultivation/manufacturing facility, they must work closely with their counterparty in coordinating the import/export administration (per product batch) and they have to contend with an annual volume based quota. For cultivation, there are only three existing cultivation licences (Aurora, Aphria and Demecan), and when operational, these producers will be mandated to sell to one buyer, the Federal Institute for Drugs and Medical Devices (BfArM), who handle the distribution. In all the above cases, a strong regulatory compliance and administrative capability is essential.

### Greek Export Pathway

In southern Europe (soon to be Europe’s cultivation hub) Greece’s medical cannabis framework is relatively simple, with a clear export-to-the-EU position being adopted. The licencing is open ended (no limit, 29 licences issued by end of 2019), fully vertical (cultivation, manufacturing and distribution permitted), with no restriction on the quantity of product allowable for manufacturing and export. Export is the only option for the foreseeable future, as the domestic medical cannabis infrastructure won’t be established for a few years. Therefore, the main strategic concern of an operator in Greece is in choosing an optimal product portfolio to produce for end medical markets like Germany.

**Exhibit 12 – Greek Legislation & Pathway example**



### Tackling Europe

Joining the dots, a US cannabis brand (say “Patton Cannabis”) could register a simple medical cannabis market-access business in Germany (as an example), positioned to import finished medical cannabis products from Greece and distribute them to German pharmacy chains as finished branded products. The regulatory framework (Exhibits 11 and 12) requires the company to hold import, distribution, narcotics trading and irradiation permits/licences before agreeing



terms with the Greek supplier. The Greek manufacturer needs to have Greek approval for production, and also produce to a sufficient standard for import acceptance by the German authorities i.e. the Greek supplier must be a Greek government approved licenced producer, with an EU-GMP certification for their facility’s manufacturing process. Patton must work in tandem with their Greek supplier for obtaining the approvals necessary to get the product order onto transport. It is more economical (in our example) for the product branding (packaging and labelling) to be done in Greece, but registration of the “Patton” brand in Germany must be obtained in advance. Finally, in Germany, a medical cannabis branded product may not be advertised to end consumers, but to healthcare professionals only.

**Quagmire Regulatory Frameworks**

More broadly, European appearances can be deceptive. On paper, Italy is the clear second largest market in Europe. However, opportunities are very restricted due to targeted legislation and restricted pathways. In Italy, the 5 licenced importers can only import from Bedrocan (Netherlands), and any other supplier i.e. Aurora Canada has to go through the Italian military (SCFM) for distribution. Historically, the tenders for the SCFM supply contracts have been tedious at best (less than 150kg has been sent by Aurora in 2 years). The SCFM happens to also be the only licenced producer in Italy, a monopoly by design (there are no commercial cultivation opportunities). By law, all end products must be sold as magistral preparations, limiting commercial distribution to whole dried flower only, as dried flower is designated solely as an API

**Exhibit 13 – Italian Government decree – Price per gram of cannabis flower at €9**

<p>Spediz. abb. post. - art. 1, comma 1 Legge 27-02-2004, n. 46 - Filiale di Roma</p>	<p>Anno 158° - Numero 127</p>	<p>Art. 1.</p>
<p style="text-align: center;">   <b>GAZZETTA UFFICIALE</b>                  DELLA REPUBBLICA ITALIANA             </p>		<p>L'allegato A al decreto del Ministro della salute 1993, recante «Approvazione della tariffa per la vendita al pubblico dei medicinali», è n come segue: dopo la voce «canfora» è inserit <b>Cannabis infiorescenze grammi 1 euro 9,00».</b></p>
<p>PARTE PRIMA</p>	<p>Roma - Sabato, 3 giugno 2017</p>	<p>Il presente decreto è pubblicato nella Gazzetta della Repubblica italiana ed entra in vigore il primo giorno dalla sua pubblicazione.</p>
<p>DIREZIONE E REDAZIONE PRESSO IL MINISTERO DELLA GIUSTIZIA - UFFICIO PUBBLICAZIONE LEGGI E DECRETI - VIA ARENULA, 70 - 00186 ROMA AMMINISTRAZIONE PRESSO L'ISTITUTO POLIGRAFICO E ZECCA DELLO STATO - VIA SALARIA, 691 - 00138 ROMA - CENTRALINO 06-85001 - LIBRERIA DELLO STATO PIAZZA G. VERDI, 1 - 00198 ROMA</p>		<p>Roma, 23 marzo 2017</p>

Source : Italian Government Gazette

for pharmacy manufacturing. Finally, as of 2017, the Italian Government fixed the retail pharmacy price of whole flower to €9.00 (Exhibit 13), severely hindering the ability of pharmacies and importers to make a viable margin. Such a regulatory framework is not exclusive to Italy; one sees similar, albeit lesser restrictions in the Netherlands (one cultivator, one purchaser for distribution) and the Czech Republic (a maximum allowable price for dried flower). The devil truly is in the detail, and prospective European market participants must be fully versed in regulatory matters before stepping ashore, or face the consequences. Already, there have been some calamitous investments, one example where a Mediterranean operator spent millions of euro in capital, built a facility and produced a product before realising that no buyer can purchase it from them (facility's process not EU-GMP approved).

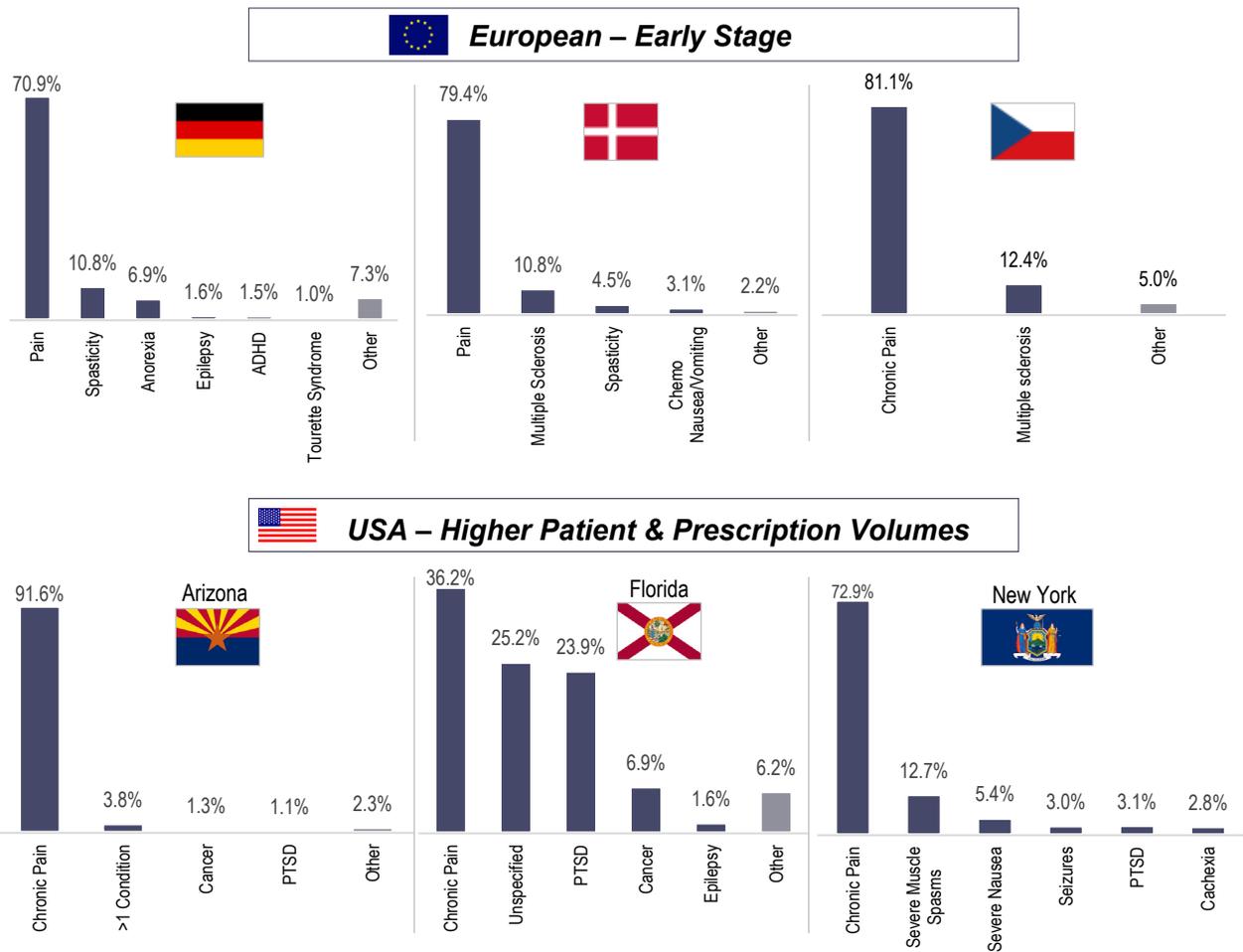
*“The devil truly is in the detail, and prospective European market participants must be fully versed in regulatory matters before stepping ashore, or face the consequences.”*

On a positive note, all of this is good news for a savvy and diligent operator. The regulatory framework challenges, once overcome, add considerable equity value to the successful company in the form of the secured commercial pathways. North American medical cannabis operating experience, combined with strong local European regulatory expertise can be instrumental in separating the wheat from the chaff.

## INDICATIONS FOR PRESCRIPTION

A medical *indication* is a condition, symptom or circumstance of a patient that makes a particular treatment reasonable. Here we look at indications for prescription of medical cannabis, consider the current state of cannabis prescribing in the EU market, and then cast an eye forward as to how the market might eventually develop.

**Exhibit 14 – European and USA indications for medical cannabis prescriptions**



Source : Regional authorities

### Current Indications

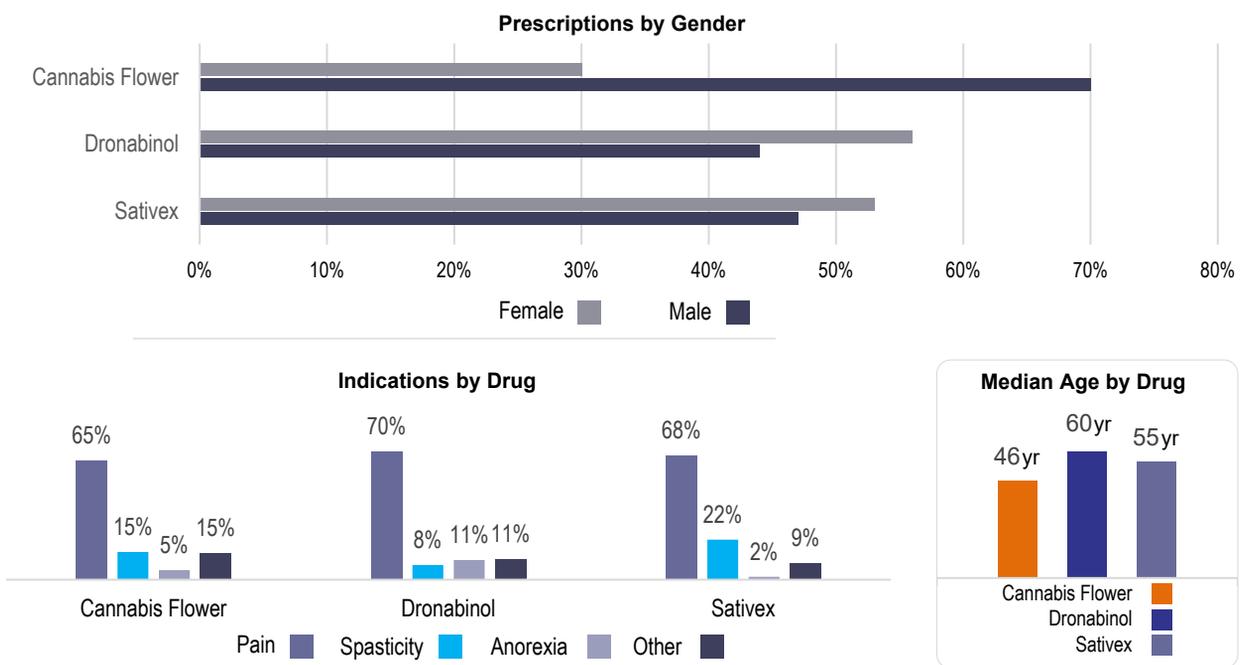
Although the shadow of illegality has slowed scientific research on cannabinoids and other derivative compounds of the cannabis plant, there is now scientifically demonstrated benefit from the use of THC and CBD medications, in various combinations. These medications are being prescribed for treatment of symptoms ranging from chronic pain to spasticity. Several

cannabinoids and synthetic analogues have been developed and approved for selected indications. As an illustration, Exhibit 14 presents charts for current prescription levels of medical cannabis in European and North American medical cannabis markets. The primary indication (70-80% in Europe) is for the management of chronic pain. Bear in mind that chronic pain comes in many forms, is caused by a variety of chronic conditions, and is a highly prevalent symptom across all general populations in the EU. For example, Leadley et al (2012)\*, in their survey of chronic pain in EU countries, found an average prevalence among adults of 27% and a cost per patient per year ranging from €1,095 in Germany for back pain to €3,246 for fibromyalgia in Spain. This is a striking illustration as to the size and significance of medical cannabis’s potential market.

### German Prescriptions

In Germany, The Federal Institute for Drugs and Medical Devices (BfArM) has been commissioned to carry out a non-interventional continuous monitoring of the use of cannabis medicinal products (due to run until 31 March 2022). They published their first report in 2019, giving us some colour behind the prescription numbers for the largest market in Europe, and

**Exhibit 15 – German Insurance Covered Prescriptions of Cannabis; 2019 Summary**



Source : Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz

\* Chronic diseases in the European Union: the prevalence and health cost implications of chronic pain  
DOI: 10.3109/15360288.2012.736933

a barometer for emerging trends in the European medical cannabis sector. Exhibit 15 shows us differences in customer characteristics between the 2 most sold products; cannabis flower and dronabinol.

Cannabis flower has a markedly younger median age (46) vs the other products, and is 70% prescribed to men. Over half of flower prescriptions co-exist alongside other therapies (such as opioid treatment). Dronabinol users have a median age of 60, with 70% of patients undergoing parallel treatment (50% of this subgroup being treated with opioids). The commonality is the dominant indication, chronic pain, which is prevalent throughout all medical cannabis products.

### **Evidence of Future Indications**

As encouraging as current indications are for the use of medical cannabis, creating deep-rooted investor interest in EU medical cannabis requires investor confidence in its substantial market potential, which in turn depends on its potential for important medical applications. The success of any proposed medication hinges on the following factors:

1. Efficacy: The medication must deliver a clinically significant benefit to patients when taken appropriately
2. Safety: The medication must be safe and have low rates of adverse events for patients
3. Prevalence: The aggregate demand for the medication must justify its development and production costs. This demand depends on the population prevalence of the indication being treated
4. Competition: The medication must offer competitive advantages over other modes of treatment for the same indication. Success of any medication depends on how its efficacy, safety and cost measure up against competing medications

The full economic potential for medical cannabis is unknown but there is a great deal of promise shown by direct and indirect scientific evidence.

**Direct evidence:** Any investor in this sector must understand the research pathway for the discovery, development and adoption of new medications. Luckily, much of this pathway is visible because of the openness of academic research and regulatory processes. The pathway is visible, yes, but it is both long and complex so one shouldn't minimize the challenges that it poses.

Today, the research pathway proceeds through the following stages:

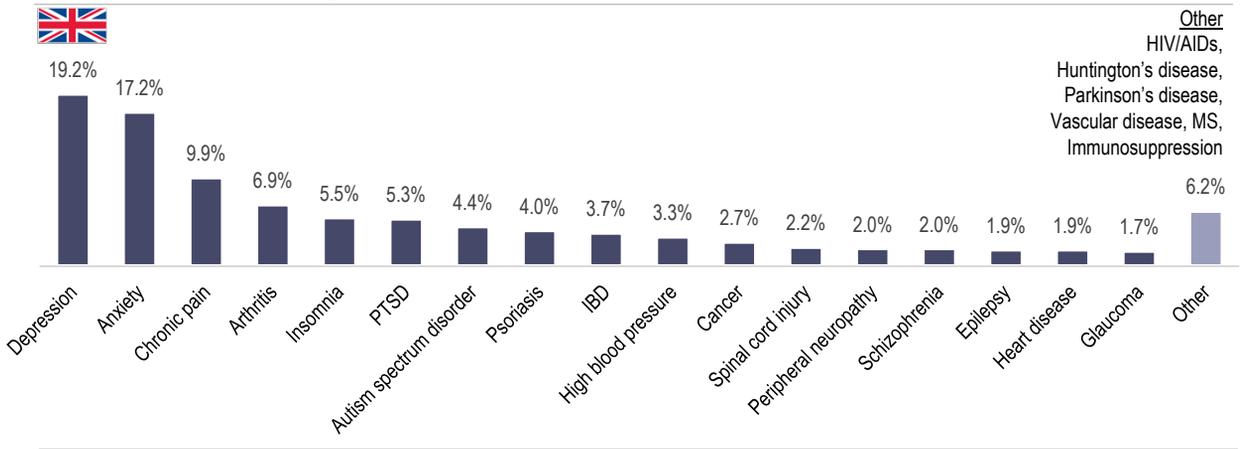
- A novel and promising research idea
- Preclinical research investigation to establish proof of principle
- Open-label studies and clinical trials to establish safety and efficacy
- Systematic reviews to consolidate evidence across supporting clinical trials
- Acceptance by a qualified medical panel and promulgated in clinical guidelines for prescribing physicians

The R&D pathway involves heavy winnowing at each stage so very few research ideas translate into medications that are prescribed. The pathway is also extremely long, difficult and expensive; each of these stages can take years of work and, thus, the product gestation period can be a decade or more.

**Indirect evidence:** The direct-evidence pathway through clinical trials is the gold standard for medical science but sources of informal evidence can provide valuable information for guiding business strategy and decision making. No medication will be adopted in clinical guidelines unless it meets the gold standard for efficacy and safety. Thus, direct evidence from well-conducted clinical trials is the final arbitrator of merit for any new medication. Informal evidence, however, can be used in several ways to compress the R&D time line. Informal sources offer clues to which research ideas may have the greatest chance of working. The sources also provide information that can help in scientific investigation, study and clinical trial design, and final product development. The sources of this evidence are of four types:

1. Traditional medicine: Medical cannabis history (Appendix I) is so long and geographically widespread that it might be viewed as a collection of large ‘informal clinical trials’. Historical records of ailments, patients selected for treatment and the modes of treatment administration is a treasure trove of evidence about potential plant-based medications.
2. Gray market: In spite of cannabis illegality, there has always been a significant gray market for medical cannabis use. The persistence of this quasi-illicit use and the associated reasons offer useful data for analysis. Exhibit 16 contains a chart showing the use of illegal cannabis for treatment of a range of medical conditions and symptoms based on a recent national survey of adults in the United Kingdom. The profile of indications being treated and the relationship of this to national prevalence rates (of said indications) point to potential future target markets. The survey is uncovering evidence from an

**Exhibit 16 – U.K. Survey of self-medicated cannabis for indications**



Source : Scale of Illegal Cannabis Use for Medicinal Intent in the UK, YouGov survey

‘informal clinical trial’ providing a snapshot of a national reality for Britons. The users have self-tested the products for adverse effects and presumably found the benefits exceed the out-of-pocket cost and offset any safety concerns. Depression and anxiety (both mood disorders) top the list in Exhibit 16, perhaps a sign of future markets to emerge beyond today’s dominant categories (such as chronic pain). Medical cannabis breakthroughs (as of yet) for these disorders are uncertain.

3. Black market: Recreational use is often a form of self-medication that meets a subliminal medical need. With further investigation, it may be determining that some of this illicit activity might be absorbed within legitimate medical treatment, that meets significant and as yet unmet health needs.
4. Discretionary prescribing: Some EU countries allow discretionary prescribing of medical cannabis. For example, Dutch doctors can prescribe unlicensed medicines available in pharmacies. This prescribing is not sanctioned by official clinical guidelines but is recognized as lying within the freedom of action of an individual physician. This prescribing is another type of ‘informal clinical trial’. The sample sizes are large and patients are supervised by the prescribing physician so adverse events are being monitored.

The future for medical cannabis in the EU depends on how efficacious, safe and competitive it is in treating important medical indications. The medical history of cannabis (Appendix I), its current use by ‘patients’ in gray and black markets, and its discretionary prescribing today in EU countries provide convincing evidence, albeit informal evidence, of its benefit to patients with various medical indications. Moreover, objective and scientifically rigorous clinical trial evidence

for significant medical application of cannabis compounds is growing steadily. But the scientific and clinical trials paradigm is time consuming and the strict reliance of clinical practice on this evidence means that breakthroughs will take time to materialize.

This slow pace is not a drawback because it gives serious players in this sector time to put the right financing, management and operating structures in place. Potential investors, looking to the EU market today, must carefully separate signal from noise in intelligence reports for this market because the signal is usually weak and subtle and always complex. Investors need to look below the surface of superficial news releases, simplistic business digests, and spotty data to understand what is really happening in this market.

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# MARKET FORECASTING

## In Bullets

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### Projections

- A Projection quickly offers a picture of the European market size and scale
- Projections are built on known information from selected leading countries
- The industry needs to move away from unrealistically large Europe Projections
- KOMAND projects the market size to surpass €1 billion by 2022 end

### Forecasts

- Forecasts are conducted by individual European country; this is not scalable
- Forecasts are more complex than Projections
- Forecasts are a necessity for a go-to-market strategy, not an option
- Scenario analyses help prepare companies for foreseen and unforeseen events

# MARKET FORECASTING

For European market entry, forecasting is perhaps more pivotal than any other input into business strategy, because it is more costly to get wrong than in the US market. Europe is far too fragmented for time to ease the pain of a misleading forecast; the revenues will not materialise sufficiently for survival. So how does one get this right? A solid starting point is to get a numeric feel for the scale of the Europe-wide opportunity by way of KOMAND Projections using “Known”s (available base knowledge). There is enough market and statistical information available in Europe to construct a picture of the future market via extrapolation, a tool to quantify Europe in a way comparable with other cannabis markets like the US and Canada.

When the time comes to get serious and commit capital to a European investment, it is necessary to conduct a KOMAND Forecast and expand into “Known Unknowns”, where more assumptions and future scenarios need to be considered. This is done on a country-by-country basis, incorporating all the Projection information and applying country specific parameters as well. Multiple future scenarios are forecasted for comprehensive business planning.



*“There are known knowns; there are things we know that we know. There are known unknowns; that is to say, there are things that we now know we don't know. But there are also unknown unknowns – there are things we do not know we don't know.”*  
– Donald Rumsfeld

Only then is a business primed and ready to take on the market knowing reasonably what to expect, with as few surprises as possible. Europe aside, an appreciation of supply and demand forecasting would have saved many cannabis businesses in the US and Canada from the current turmoil they are experiencing. The disconnect between capital expenditure and current revenues should not be a revelation. From now onwards, the North American survivors (and winners) are the ones who took measures to tailor their growth spending to accurately forecasted revenues. Thankfully, we have been given a second chance in Europe, a chance for investors to get this right.

## PROJECTIONS - EXPLOITING THE KNOWN

A KOMAND Projection is a simpler version of a Forecast in which Known information i.e. prices, patient data, product portfolios from leading European markets (Lead Countries) is combined with simple but reasonable assumptions to extrapolate the future size of nascent European markets (Dependent Countries). The Lead countries are data-rich countries like Germany, Denmark and Netherlands. Exhibit 17 presents KOMAND Projections based on this extrapolation method.

### *Exhibit 17 – Sample KOMAND Projection, based on extrapolation method*

2022 European Market Projections				
Country	Population	2022 Patient Census*	2022 Market Size	Active Quantity (THC & CBD)
Germany†	83.02m	194,000	€390m	2,470 kg
Denmark†	5.81m	13,000	€30m	175 kg
Netherlands†	17.28m	39,000	€80m	490 kg
France	67.03m	38,100	€90m	510 kg
United Kingdom	67.89m	38,800	€92m	520 kg
Ireland	4.90m	2,800	€7m	38 kg
Spain	46.93m	28,200	€66m	375 kg
Czech Republic	10.65m	6,500	€15m	86 kg
Poland	37.97m	23,300	€54m	309 kg
Italy	60.36m	36,500	€85m	479 kg
Switzerland	8.53m	5,200	€12m	69 kg
Romania	19.40m	12,800	€28m	156 kg
Belgium	12.47m	6,800	€16m	90 kg
Greece	10.72m	6,400	€15m	85 kg
Portugal	10.28m	6,200	€14m	82 kg
Sweden	10.23m	5,900	€14m	79 kg
Hungary	9.80m	6,000	€14m	79 kg
Austria	8.86m	5,400	€13m	71 kg
Bulgaria	7.00m	4,300	€10m	57 kg
Finland	5.52m	3,300	€8m	43 kg
Slovakia	5.45m	3,400	€8m	45 kg
Croatia	4.08m	2,500	€6m	33 kg
Lithuania	2.79m	1,700	€4m	22 kg
Slovenia	2.08m	1,300	€3m	17 kg
Latvia	1.92m	1,200	€3m	15 kg
Estonia	1.32m	800	€2m	10 kg
Cyprus	0.88m	700	€2m	10 kg
Luxembourg	0.61m	400	€1m	5 kg
Norway	5.34m	3,100	€7m	42 kg
N. Macedonia	2.04m	1,300	€3m	17 kg
Malta	0.49m	300	€1m	16 kg
<b>Total</b>	<b>530.65m</b>	<b>498,200</b>	<b>€1,093m</b>	<b>6,495 kg</b>

\* Patient Census is the number of patients who are using prescribed medical cannabis on a specified date

† Lead Countries for this sample KOMAND Projection

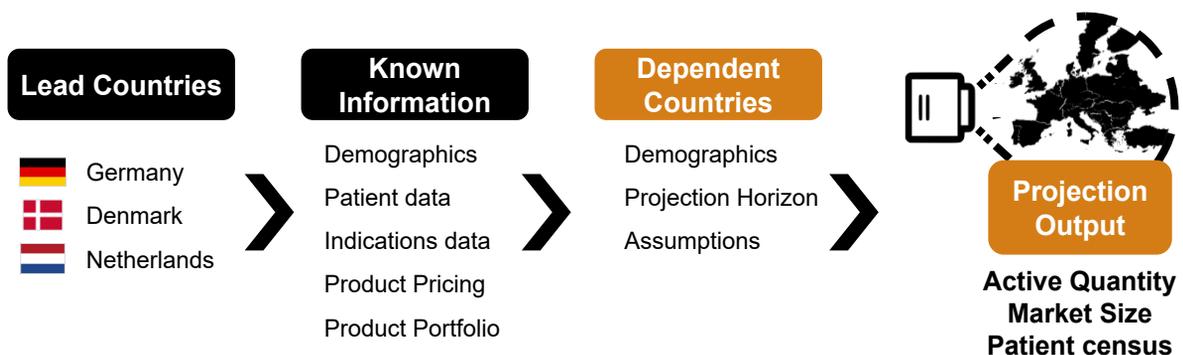
Exhibit 17’s “Active Quantity” output (for each country) refers to the aggregate active ingredient (THC & CBD) that will be demanded by each market. This is the same “milligrams sold” convention as seen in Danish reporting (Exhibit 5). Active Quantity is derived from aggregated patient indications (reasons to prescribe medical cannabis, see below).



### The KOMAND Projection in 5 Steps

1. Use a representative set of medical indications being treated
  - Estimate the prevalence of these ailments among age-sex subgroups of the population
2. Assume appropriate medical cannabis prescriptions for the ailments
  - Estimate subgroup response and uptake percentages of cannabis treatment for each ailment
3. Take a representative product portfolio (from Lead Countries) covering the THC/CBD spectrum
  - Characterize each product by its pure quantities of THC and CBD
4. Use available product price data (retail prices across categories, including VAT, per milligram)
5. Carry through the accounting to estimate patient counts, active ingredient quantities (THC/CBD amounts) and gross sales for each country

**Exhibit 18 – KOMAND Projection data flow**



The Projections in Exhibit 17 have a relatively short time horizon, year 2022. An assumption has been made that by 2022 the Dependent Countries will catch up with today’s Lead Countries in terms of demand and available products, resulting in a 2022 aggregate market size of €1.1bn.

This market projection is a realistic base point for near-term medical cannabis sales in Europe. It is concerning to see many retail cannabis publications predicting a €30bn+ European medical cannabis market by 2024, discredited if one conducts any simple analysis.

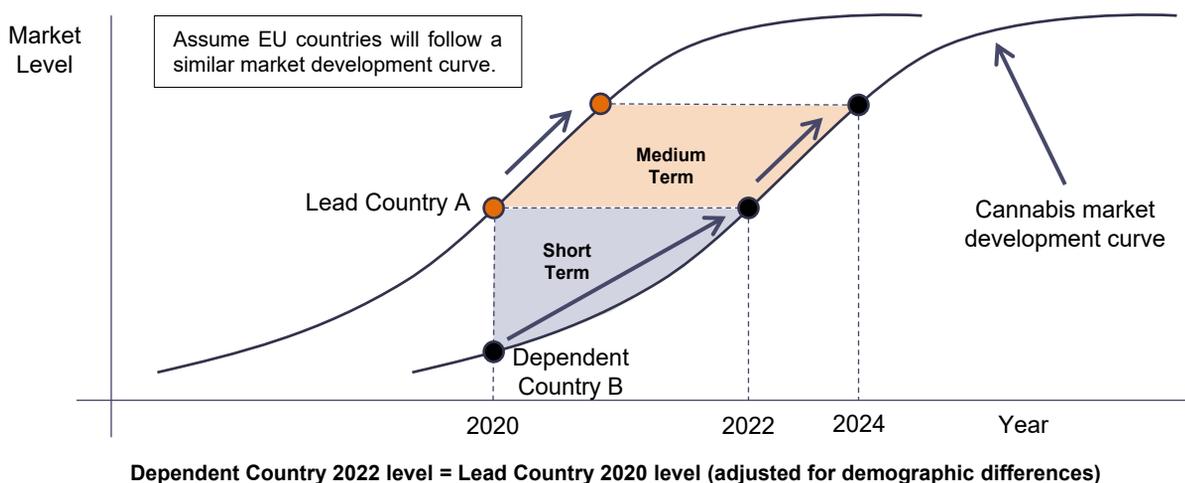
### Moving Beyond the Short-Term

The time horizon of 2022 in Exhibit 17 was selected to be the year that Dependent Countries will catch up with the Lead Countries. As a Projection’s time horizon is extended, assumptions must be made for the Lead Countries before applying the extrapolation process. Additional assumptions include;

1. Demographic and population prevalence assumptions
2. Assumed indication lists (conditions and symptoms)
3. Trend estimates of response and uptake across the indications
4. Price estimates
5. Estimated changes in the proxy product portfolio over time

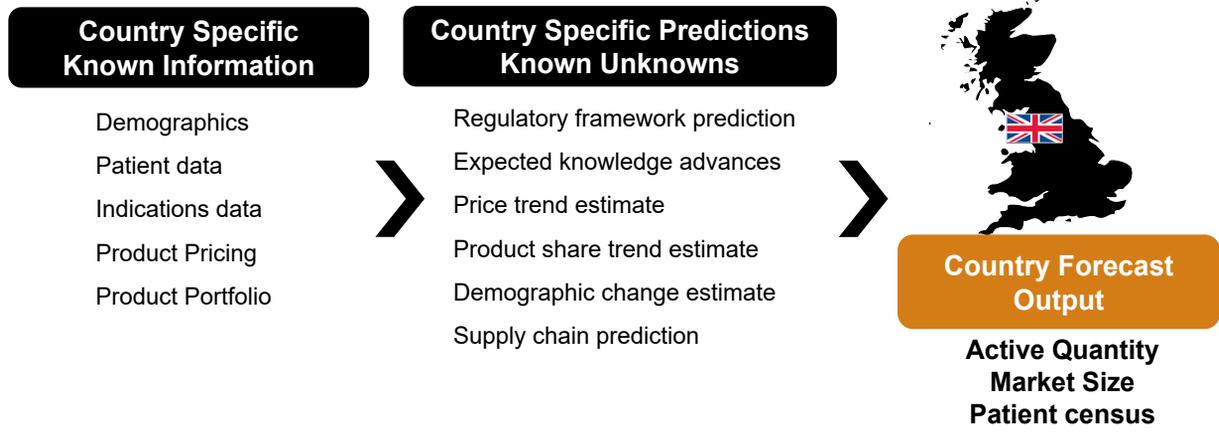
For example, response and uptake estimates for indications depend on evidence from clinical trials and systematic reviews. Uptake is partly determined by the competitive position of medical cannabis among all possible treatment modes for each indication. As the Projection horizon becomes more distant, more assumptions are needed about the market development curve for both Lead & Dependent Countries (Exhibit 19). At this point, a KOMAND Forecast is warranted.

**Exhibit 19 – Projection methodology; EU market convergence assumption**



## FORECASTS - EXPLORING KNOWN UNKNOWNNS

*Exhibit 20 – KOMAND Forecast methodology data flow*



KOMAND Forecasts address European countries individually, with analyses, assumptions and predictions prepared for each country. This level of detail is needed for go-to-market strategy planning for a single country or pan-European entry planning, and should be conducted before committing any capital to the strategy. While Projections paint a European future on a broad canvas, Forecasts focus on deeper market intelligence and best decisions for capital deployment.

Key Forecast elements (“Known Unknowns” in Exhibit 20) are used in addition to Projection elements, and include the following;

1. Regulatory Framework
  - Estimated timing of regulatory progression e.g. medical cannabis legalisation
  - Regulatory factors limiting the market size e.g. Italian price limit of €9
  - National health insurance policy
2. Knowledge advances
  - Extension of treatment to new conditions and symptoms
  - Advances in scientific evidence, such as clinical trials
  - Updated and/or expanded clinical guidelines
  - Discovery of efficacious cannabinoid compounds beyond THC and CBD
  - Emerging evidence of adverse side effects
3. Price changes and shifting market shares
  - Magistral preparations replaced by mass-produced equivalents
  - Substitution of generics for branded products
  - Effects of promotion and market competition on prices and shares

4. Demographic changes and indication prevalence
  - Population size and indication subgroups
  - Age profile shifts
5. Supply chain changes
  - Trends in synthetic versus plant-based products
  - Hemp sources of CBD
  - Commodification of medical cannabis
  - Out-sourcing of supply to low-cost countries
  - Quality assurance protocols

In summary, the Forecast process is more intensive than the Projections, and not as scalable, as country-by-country Forecasts are entirely separate processes. While Projections can give a feel for the aggregate market size, basing strategic planning on this is shallow and short-sighted as the deep drilling required can only be addressed by Forecasts. Ultimately, capital investments should incorporate more depth and realism into decisions for more targeted opportunities.

Finally, concerning the remainder “Unknown Unknowns”, some things in life are so unexpected that it is not possible to fully prepare for them. To mitigate, there is merit in formulating strategies that are designed with some pure uncertainty in mind, and in building robust organizational and financial structures that can withstand shocks and disruptions. Taking forecasting models, and running various scenario analyses assist in planning for “Known Unknowns”. But this also better prepares the business for possible “Unknown Unknowns” lurking in the long grass.

In the context of the global cannabis industry, COVID-19 , with its associated effect on the supply chain, is such a disruptive occurrence. The pandemic, however, would have had some overlap with a “Recessionary Event” in scenario forecasting, and pre-planning for general disruption would have come to fruition now. It is already evident that the superior business planners in North America will emerge even stronger. More than ever, high quality forecasting has proven its merits.

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# INVESTMENT IN STRATEGY

## In Bullets

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### Business Fundamentals

- To date, European cannabis businesses have not prioritised strategic planning
- The Field Model is fundamental in formulating competitive business strategy
- The *how* and *where* to compete should be well defined for each company

### The 6 KOMAND Strategy Archetypes

- Specialisation is an absolute must in the European cannabis market
- KOMAND has an iterative selection process to categorise a company's strategy
- 6 strategy archetypes have been identified to succeed in Europe
- If a company is positioned too broadly across the value chain, it will fail

### KOMAND 6-Arch™ Applied

- Vertical integration in Europe is ill-advised and not necessitated by licencing
- This is conventional business wisdom, illustrated throughout history
- Case Study: The 6-Arch model is applied to an active European operator

# INVESTMENT IN STRATEGY

In corporate finance and investment management, traditional investment analysis is built on historic benchmarking in some form. For valuation of an opportunity, comparatives are sought or a discount factor can reflect the opportunity's risk level based on market rates. Long story short, valuations and decisions are made now on information derived from the past.

However, for a new industry in its infancy, there is no such information to rely on. How did one value a dot-com business in the late 1990s? Sadly, at that time, investor enthusiasm and investment-advisor reliance on conjecture resulted in painful losses. A poster child for the burst bubble was "Pets.com". It went public in 2000 to much fanfare, with huge brand awareness (the sock-dog was on a Superbowl commercial and in Macy's Parade). However, their business plan was terminal, designed to lose money on every sale, and no independent market research had preceded their launch. Pets.com's demise was a famous reiteration of the importance of paying heed to simple business fundamentals.



Pets.com sock puppet, a symbol of the dot-com bust

KOMAND sees the current global cannabis industry in much the same way. The North American boom-bust cycle of 2019 does not provide for reliable European benchmarking, and the analysis is further exacerbated because of all the aforementioned European peculiarities in the Market Conditions section of this paper. European opportunities need to be screened and scrutinised on business strategy based on business fundamentals. Making "Investment in Strategy" a priority in one's investment strategy will separate future big-winners from future sock-puppets.

In this "Investment in Strategy" section, KOMAND outlines the European cannabis industry's first systematic approach to assessing companies' business strategies.

## **BUSINESS FUNDAMENTALS - FIELD STRATEGIC FIT MODEL™**

Proven business strategies can determine what successful companies should look like in the European cannabis sector. Evaluation of businesses through the lens of the Field Strategic Fit Model™ (Field Model – Exhibit 21)\* helps organizations determine how to strategically position in their competitive environment for long-term profitability. The model requires the alignment of

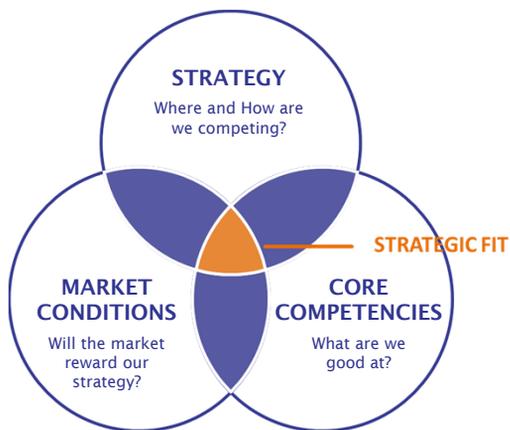
\* The Field Strategic Fit Model™ was originally developed by Tim Field, a professor at the John Molson School of Business (Concordia University) and a partner at KOMAND Consulting

three key elements – **Market Conditions** ↔ **Core Competencies** ↔ **Strategy** – to give **Strategic Fit**. Strategic Fit is achieved when an organization has selected a competitive strategy that will be rewarded by the market in light of current realities and possessing the appropriate competencies to execute the strategy. ‘Market Conditions’ are the external, uncontrollable realities, which set the playing field for all competing organizations. ‘Core Competencies’ are typically developed over time with substantial investment and accumulated experience, and are more difficult to subsequently alter. The ‘Strategy’ is the most dynamic element where successful formulation can lead to sustained profits, while miscalculations will result in substantial capital losses and worse.

## Market Conditions

Without a good understanding of the prevailing market conditions, it is impossible to steer a business in the required direction at any particular time. It is critical to evaluate the current state of and future changes in the regulatory environment, industry value chain, customer segments,

### Exhibit 21 – Field Model



product trends, market demand and competitive environment for tactical and strategic decision making. European Market Conditions (opening section of this paper, summarized in Appendix II) point out highly significant intricacies to take into consideration before Europe-entry planning, many of which make such planning distinctly different than in the USA or Canada (the key differences are laid out in Appendix III).

In a mature market, evaluating competition is usually top priority, but European medical cannabis is sufficiently young for the market to be wide open (much “white space”) in which to choose to compete. This lack of incumbent competitors is very attractive – current competition isn’t as major a driver for strategy design.

## Core Competencies

Every company has their unique blend of resources and capabilities, a combination of balance sheet assets (tangible and intangible), systems, processes and people. The resulting combination

forms a company's core competencies – what it does exceptionally well to deliver on its value promise. Over time, this leads to a sustainable competitive advantage - maintaining an ability to do something better than everyone else in the market.

In the nascent European cannabis industry, we see 2 types of companies:

1. start-up companies and 2. related-sector companies e.g. pharmaceuticals diversifying into the cannabis sector. Start-up companies make investments in resources and capabilities in the hope of building core competencies. Related sector companies have already established core competencies, which they attempt to transfer into the cannabis sector. Generally, related-sector companies that can effectively transfer their pre-existing competencies into the cannabis sector will fare better than the start-ups.

## Strategy

The final Field Model element revolves around *how* the company intends on winning and *where* it intends to win. The how determines a company's strategic position in the market – will it be a low-cost mass producer of white-label goods? Will it focus on a specific market segment and deliver premium products to a select few pre-established relationships? The where refers to domains in which it operates – Which countries? Products? Customers? Value chain segments? Most European cannabis companies are lacking in clear and well defined long term strategies. The Field Model is instructive for such companies, and lays the foundations for building of an “Investment in Strategy” benchmark tool, explained in the following section.

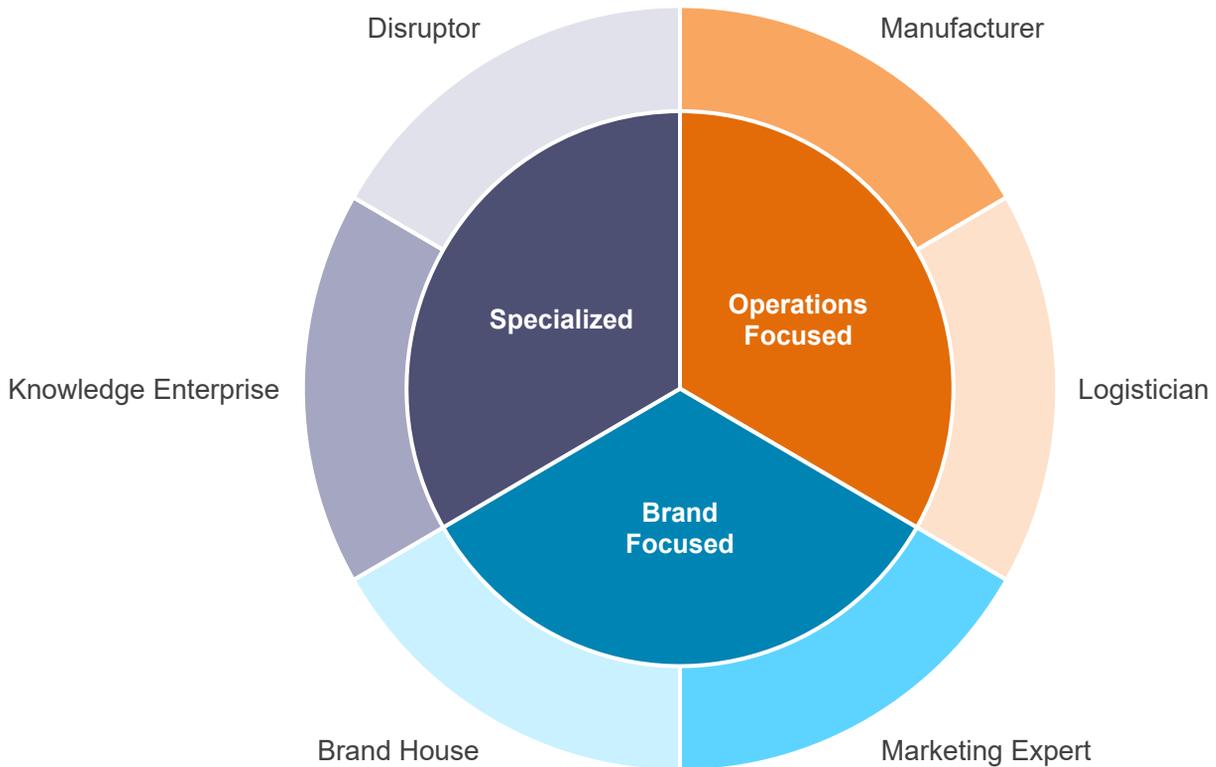
## **KOMAND'S 6 STRATEGY ARCHETYPES MODEL (6-ARCH™)**

KOMAND's 6 Strategy Archetypes Model (6-Arch™) has been developed as a filter to help financial investors identify the winning strategies in which to invest, to encourage cannabis operators to better articulate their strategy and to guide related-sector companies in carefully deploying their capital when entering into cannabis. All participants seek the crystal ball to reveal what a future winning company looks like (Exhibit 22).

To tackle this, the filter identifies only viable business models (the “Archetypes”) for the European market when accounting for structural realities and fundamental business principals. Field Model principles are applied, incorporating the current state and future direction of the European cannabis market (“Market Conditions” and “Market Forecasting” sections in this

paper). KOMAND has identified 6 Archetypes that will position companies to succeed in Europe.

**Exhibit 22 – KOMAND's 6-Arch™ layout**



## Forming 6-Arch

To start, there are 3 mutually exclusive broad strategic positions (“Focuses” – Operations Focused, Brand Focused and Specialized) before finalising on the more specific 6 Archetypes (2 per Focus). While a company may evolve within its Focus and diversify/integrate to be positioned as both Archetypes, it is ill-advised for it to operate outside its core Focus e.g. an *Operations Focused* company deciding to become *Brand Focused*.

### 1. Operations Focused

These companies are strategically positioned to deliver products and services on a mass scale, and are typically capital intensive companies that have developed superior capabilities in operational effectiveness with low labour costs. As the European cannabis market continues to grow and

logistical pathways remain challenging (from a regulatory perspective), there will be an increasing need for pure play white-label companies that are service-oriented more so than brand focused. A company that positions itself as a cost-leader in any of the upstream activities such as cultivation, processing, and logistics will be in high demand. For example, a cultivator that specializes in supplying granulated flower as a bulk active pharmaceutical ingredient (API) will be an important actor when the market size for that particular product category surpasses the billion Euro mark, where even a 1% decrease in cost-of-goods-sold results in tens of millions of Euros in savings.

#### Archetype 1 – Manufacturer (Exhibit 23)

Manufacturers are operators whose objective is to mass produce cannabis-related products, typically on a contract basis. Manufacturers can focus on one or two activities in the value chain, such as flower cultivation, full-spectrum oil extraction or packaging. Their core competencies (and potential competitive advantages) lie in operations and supply chain management. The majority of their capital investments will be in advanced manufacturing equipment.

An example 6-Arch Manufacturer in Europe is Linneo, based in Madrid, Spain. Linneo (and its parent company, Alcaliber) focus on supplying white label cannabis products to the European market.

#### Archetype 2 – Logistician

These are operators that play a more traditional distributor role in the market, managing a large portfolio of multi-brand products. To excel, these companies focus on basic elements (no-frills, reliability) in their offerings that satisfy the requirements of their chosen EU markets. Long term, the key to success is addressing the needs of the masses while keeping costs to a minimum.

A cannabis logistics company focusing on one or two large markets in Europe e.g. Germany and the U.K. fits this Archetype well. The company has a registered fleet of vehicles outfitted for a specific product portfolio cleared (regulatory pathways open) for a few key countries. The higher the volume they deliver, the lower their unit costs.

An example Logistician in Europe is the Phoenix Group, a German pharmaceutical distributor. Phoenix has managed the logistics for product transportation, positioned as a low-margin, high-volume business, with gross margins averaging at approximately 4%.

## 2. Brand Focused

Brand focused companies target the end consumer (patient) and have a strong pulse on market demand. They use their superior market knowledge to invest in acquiring or licensing products for target segments they have access to. The European cannabis market poses challenges in selling branded pharmaceutical narcotic products in different jurisdictions, and companies in this group must possess capabilities in accessing the various EU jurisdictions with branded pharma products. When pre-existing pharmaceutical companies enter the cannabis sector, they will position themselves based on one of the two archetypes in this group.

### Archetype 3 – Marketing Expert

A Marketing Expert relies on external R&D to develop the products for their branded line. They typically commission contract manufacturers to produce the products for their brand before distribution throughout Europe. Their core competency lies in customisation of finished branded products to satisfy local market demands. Such companies may eventually decide to take on more activities in the supply chain including owning their own product testing facilities and warehouses to complement or augment the core competency.

An example Marketing Expert is Fagron NV based in the Netherlands, backed by an incumbent pharmaceutical-brand company with a pre-existing product portfolio.

### Archetype 4 – Brand House

If a multi-national pharmaceutical company decides to enter the cannabis sector, this would be their preferred archetype. A Brand House goes beyond the activities of a Marketing Expert in that they commission clinical trials and own the intellectual property of the portfolio products. They may also be involved in later-stage, specialized manufacturing functions such as product formulation. These companies register their brands in all of the major European markets.

An example Brand House is a large pharmaceutical company like Sanofi, looking to enter the cannabis space. This is evident in its registered cannabis-related clinical trials (Exhibit 10). When the time comes, Sanofi's existing sales, branding and distribution capabilities will be quickly exploited to sell its cannabis portfolio products.

### 3. Specialists

The Specialist company has a much narrower focus than the others, with heavy emphasis on R&D and intellectual property. For example, one may focus on a specific therapeutic area or technology but have identified a real market need that needs solving or addressing. Common capabilities for each successful 'Specialist' archetype include the ability to recruit and manage highly sophisticated personnel and coordinate research and development activities. These are the companies that will focus on a specific, narrowly defined problem facing the European cannabis sector.

#### Archetype 5 – Knowledge Enterprise

These companies have the ability to monetize unique and deeply acquired cannabis knowledge. Their knowledge acquisition and distribution methods may vary and can be completely virtual, requiring capabilities in the digital domain, or physical, which will require capabilities in personnel management and project management.

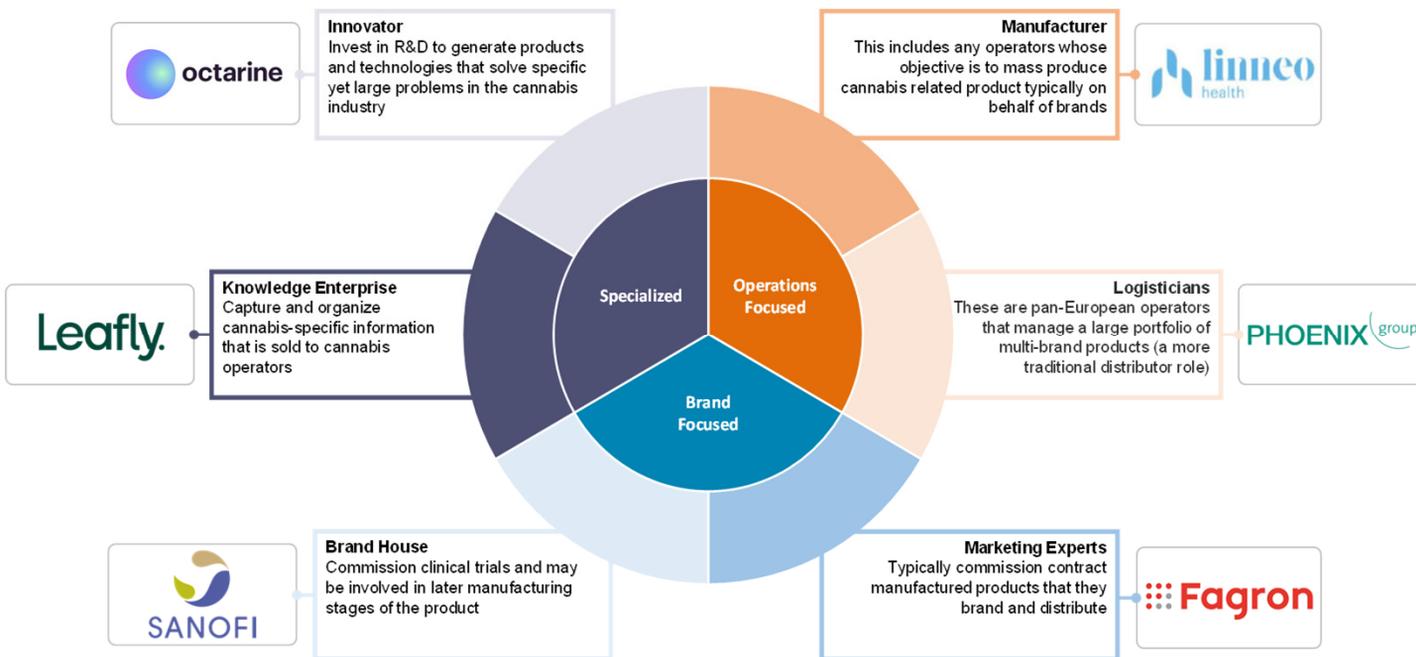
An example is the digital cannabis product information company, Leafly, having established a system to capture unique product knowledge, which it then sells to cannabis producers (and other operator types). Leafly are North American and would be entering into a European market where a similar business does not currently exist.

#### Archetype 6 – Disruptor

The Disruptors can be game changers in the industry. They invest the majority of their capital in R&D to solve a specific yet large problem facing the industry. These companies don't have the ability to mass scale and will typically pursue a licensing model to generate revenue, hence minimizing operational risk.

An example Disruptor is the European biosynthesis company, Octarine Bio. Octarine "harnesses synthetic biology to develop functionally superior cannabinoid and psilocybin derivatives" ([www.octarinebio.com](http://www.octarinebio.com)). They seek to solve the biosynthesis commercial viability problem and if they succeed, their technology will eventually be licensed by 6-Arch Manufacturer companies.

Exhibit 23 – KOMAND's 6-Arch™ examples



### Go-To-Market Strategy

With a 6-Arch strategic position chosen (the “How”), the company can focus on its operating domains (the “Where”). Management needs to carefully choose geographical markets, customer segments, product categories and therapeutic areas, based on a deep understanding of good information. The deeper the understanding, the better these choices will pan out.

For example, a 6-Arch “Marketing Expert” could choose to focus on selling medical cannabis products to the elderly in Europe, in promotion of a functional status and quality of life. Research would enquire on regions/countries with a strong infrastructure for supporting the elderly e.g. publicly-funded long-term care facilities, public insurance policies and delve into data on the prevalence of indications in the elderly population. A possible result would be choosing to market an oral solution in Germany for the indication “Chronic Pain” to new elderly users of medical cannabis as an alternative to other pain medication e.g. opioids.

Ideally, with a perfect understanding of their domains, companies will send perfectly timed and appropriate products for the highest penetration in their chosen markets.

## 6-ARCH APPLIED

The 6-Arch assessment can be used by investors to filter new European investment opportunities, enabling money-in investors to reassess their current European holdings and to help companies' management teams in prioritising strategy. The following two examples offer critiques of strategy based on 6-Arch principals.

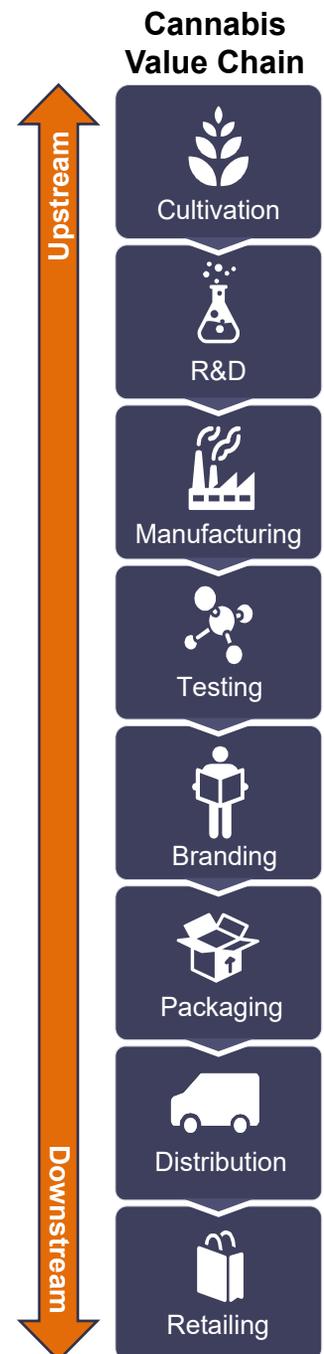
### Vertical Integration Debunked

Operating a fully vertically integrated company, profitably, is a tall order in any industry. Yet for many cannabis companies it has been a go-to strategy from initiation. They are attempting to incorporate all of the capabilities across the cannabis value chain (Exhibit 24), resulting in a 6-Arch position of being all 6 Archetypes at once. This is unrealistic strategically in the sense that historically companies have needed decades of operating experience and market growth before vertical integration makes sense for sustainable success.

For perspective by example we can look at Ferrero, a famous Italian confectionary group operating in a mature industry. It took Ferrero, owner of brands like Nutella® and Ferrero Rocher® (annual revenues \$12bn+) almost 70 years before deciding to backward integrate into supplying its own hazelnuts (a key ingredient in their chocolate) and purchasing an established hazelnut manufacturer. The motivation for the integration wasn't for increased profit margins – a market-leading company like Ferrero is sophisticated enough to recognize that the probability of increasing margins via an upstream acquisition is quite low. Post-merger integration is challenging, and Ferrero's core competency is in chocolate making (not hazelnut growing).

Instead, Ferrero's motivation for the upstream acquisition was a response to an exceptional increase in consolidation of hazelnut manufacturers. To sit idly by would have exposed Ferrero to increasing hazelnut prices, and the move was a risk mitigating necessity to

**Exhibit 24**



continue delivering exceptional chocolate products at an acceptable retail price.

Sometimes in the cannabis industry, vertical integration is a result of legislation rather than a strategic choice. Trulieve, the leading light in Florida, USA, is such an example. It has been a stellar performer (+45% for stock price 2019, they own 50% of all sales in Florida) in a state which forces Licenced Producers to grow the cannabis that they sell in their retail dispensaries. However, this successful Florida vertical integration story will not serve as a successful blueprint in Europe, and KOMAND generally argues that unless the subject jurisdiction forces a fully integrated model, there is no clear case to be made for it.

For the European cannabis market, a capital-intensive vertically integrated approach is further exposed to the current limited market size, and the differing regulatory environments of the respective end markets. The large capital investment required to establish capabilities for every function in the value chain e.g. cultivation, processing, formulation, branding, sales, distribution is not justified by the projected increase in revenues, if any.

### **Bedrocan - 6-Arch Manufacturer**

Bedrocan, the Dutch cannabis flos (flower) manufacturer, is the most widely known cannabis brand and biggest selling producer in Europe. They have been producing standardised legal medical cannabis since 2003, also making them the world's most experienced commercial cannabis flower producer. Their market share stands at approximately 50% of all sold dried flower in Europe (see Exhibit 7).

At first glance, one could be forgiven for assigning Bedrocan the 6-Arch Brand House Archetype, seeing as they do have the best known branded product line in Europe (see "Medical Cannabis Products" section for examples) and they own the intellectual property (the strains) of their products.

However, a lengthier look at Bedrocan concludes that the core competencies lie upstream, in cultivation and mass production, and not downstream, in sales and marketing. The competitive advantage hinges on its long production history leading to its ability to produce consistent, stable products on a mass scale. In fact, Bedrocan's sales process, pricing, packaging and exports are all outsourced (by mandate) to the Dutch Office of Medical Cannabis (OMC). This falls in line with

the strategic positioning and capabilities of the 6-Arch “Manufacturer”. Bedrocan’s brand equity, although strong, is a consequence of Manufacturer capability more so than an effect of sales and marketing superiority.

As a private Manufacturer looking to defend a leading market position, it would be appropriate for Bedrocan to consider establishing a large-scale cultivation and production facility in a low-cost European country with favourable climate conditions and cannabis regulations i.e. Greece, Spain or Portugal. Other strategic options for Bedrocan include focusing more on a white-label product offering or forward integration into mass full-spectrum oil and isolate production.

Choosing the right strategic option, by focusing on their advantageous 6-Arch Manufacturing position gives Bedrocan the best chance to maintain a leadership position as the leading supplier of reputable cannabis raw material inputs. The logical strategy would be to increase Europe-wide manufacturing capacity, maintain quality of production and focus on business-to-business white-label sales. Investing heavily in the brand itself will result in a showdown with the pharmaceutical behemoths in the not-so-distant future.

The Bedrocan CEO, Tjalling Erkelens, is contemplating these decisions, as he states in his response to a question from KOMAND’s TJ Unger (The Cannabis Conversation, Episode #68, minute 45).

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# CONCLUSION

Once one can start to appreciate the earnest challenges in entering the European market, any initial hopes for a field of dreams i.e. “Build it and they will come” are dashed by the realities of a fledgling industry trying to break down the regulatory, commercial and cultural barriers stifling market growth. Being first-to-market is not enough to win, and without a well positioned strategy, not enough to survive.

This in itself is the biggest opportunity. If an investor can deploy time and effort in considering strategy and thoroughly understanding the European market, then they are buying in at a discount to their peers, as the market has not yet priced in strategy. Over the next decade, as the market matures, the leading companies will fall into the 6-Arch positions, with successful strategies fully realised in valuations.

When the dust has finally settled in the European medical cannabis market, many choices for businesses will be seen as obvious in hindsight. Investment in Strategy will most certainly be on the “Hindsight is 20/20” showreel.

*“The early bird gets the worm, but the second mouse gets the cheese.” - Willie Nelson*

# APPENDIX I

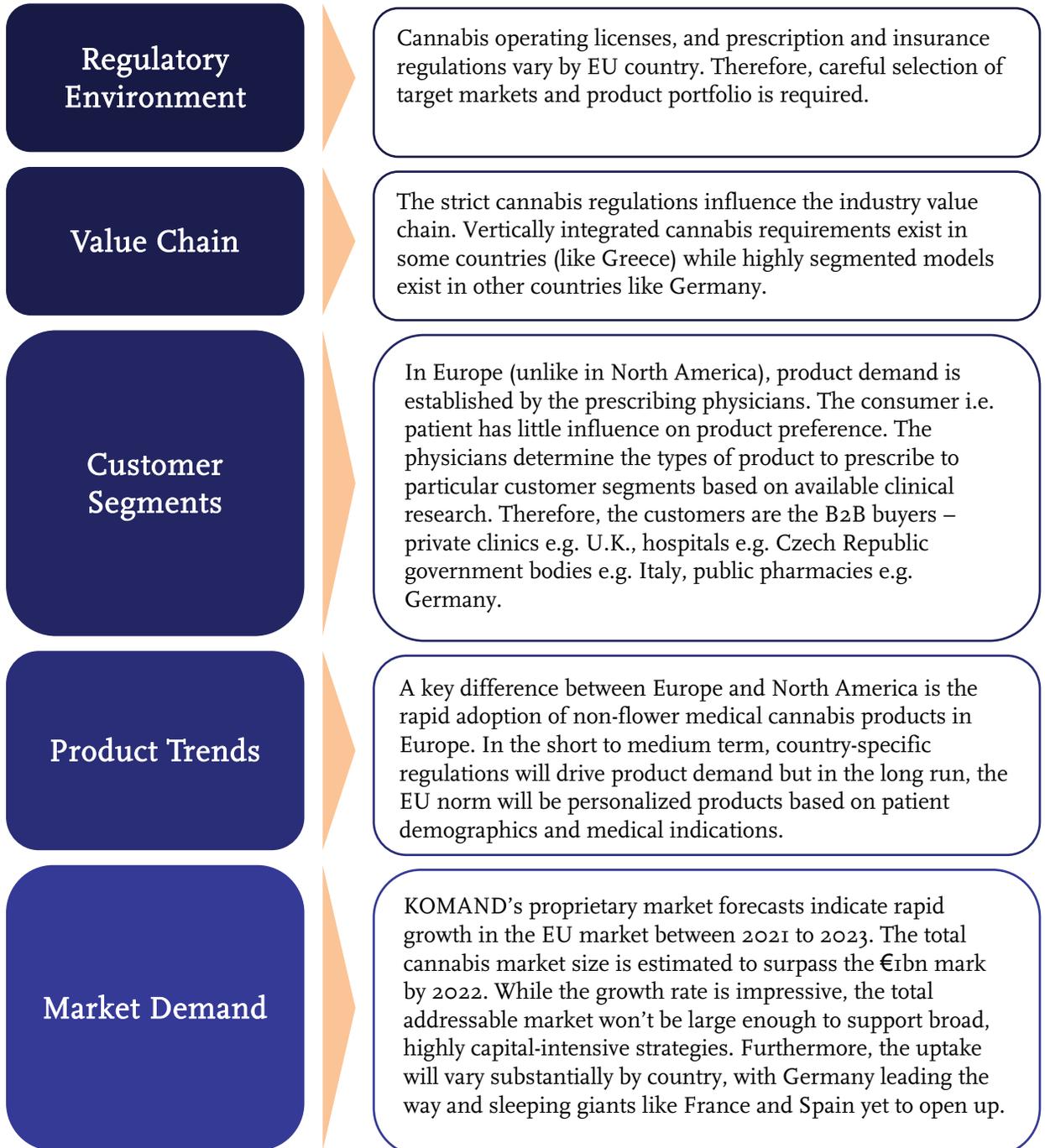
## **The History of Cannabis as a medicine**

The marijuana plant has provided important medicines for many ailments since ancient times. The fact that its medical use spanned diverse early civilizations from China to Egypt shows that its value for treatment was recognized from prehistoric times. Historically it was used as an analgesic, anesthetic, diuretic, anti-inflammatory, and in numerous other applications. Use was made of every part of the plant. Its flowers, seeds, stalks and roots were all processed, prepared and administered in diverse ways for healing. Its psychoactive properties were also understood and used medically. The medical history of the plant is not simply an interesting story but, as we consider later, can serve as a suggestion box, catalyst and guide for more recent scientific advances in medical cannabis.

In spite of its historical importance as a medicine, the psychoactive properties of cannabis gradually led to its almost complete ban worldwide and its international listing as a controlled narcotic. Global restrictions on its production, distribution and use started almost 200 years ago. For the USA, legislative controls on marijuana started in 1937. Only in the last two decades, when the medical value of the plant has again been recognized, have bans been relaxed. With advances in plant science, biochemistry and medical science, we have gained a more sophisticated and refined appreciation of the potential of marijuana-based compounds for efficacious treatment of medical conditions and symptoms. The plant has scores of important compounds, including cannabinoids, terpenes, and others, as well as many derivative compounds, associated metabolites, and the like, that may be sources of safe and effective medications.

# APPENDIX II

These are the major conclusions from the European market and their strategic implications.



# APPENDIX III

Comparison of the North American and European market structure. The orange shading illustrates commonalities in a particular dimension between two markets.

	USA	Canada	Europe
<b>Regulatory</b>			
<i>Product Market</i>	Medical and Recreational	Medical and Recreational	Medical Only
<i>Licensing</i>	Local (state) level	Federal (except retail/dispensary which is local)	Local (country) level
<i>Insurance</i>	Not covered under federal programs	Covered under public insurance	Country-by-country
<b>Go-To-Market</b>			
<i>Geographical Expansion</i>	No interstate trade	Federal (interprovincial) trade allowable	Intra-European trade allowable
<i>Market Potential</i>	\$30-37bn by 2024	\$5-6bn by 2024	\$2-4bn by 2024
<i>Product Portfolio</i>	Majority dried flower	Majority dried flower	Majority extracts and isolates
<i>Channels</i>	<ul style="list-style-type: none"> <li>- Consumer/patient access from state appointed, cannabis-specific stores i.e. dispensaries</li> <li>- E-Commerce (state-by-state)</li> </ul>	<ul style="list-style-type: none"> <li>- Consumer/patient access from Provincially appointed, cannabis-specific stores i.e. dispensaries</li> <li>- E-Commerce</li> </ul>	<ul style="list-style-type: none"> <li>- Traditional retail i.e. pharmacies</li> <li>- Clinics/hospitals (on-site pharmacies)</li> <li>- Brick and mortar only</li> </ul>
<i>Majority Consumer</i>	Millenials(<35), Male	Millenials(<35), Male	Generation X (40-55), Male

Sources : StatCan, MJBiz, BDS Analytics, KOMAND

# ABOUT THE AUTHORS



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