



Germany

1. Market Overview



Germany boasts the largest economy in Europe - a global leader across multiple industries and the forerunner of the European cannabis industry.

Germany, Europe's largest potential market opened up in March 2017 with the introduction of new medical cannabis legislation and the creation of eleven production licences. The system to allocate licenses was geared towards experienced international companies partnering or creating joint ventures with local companies. The country's wealth of talent and resources is set to ensure that this market will become a global standard in the future. However a series of controversies means that a re-evaluation of the application process is due imminently ([see Expert Input](#)).

Recreational use is currently illegal in Germany, although punishments have become increasingly lenient in recent years as attitudes shift. While dwarfed by France, Germany's industrial hemp production industry is in the top five in Europe and is expected to grow in 2018. The country is poised for further reform, including decriminalisation which was called for by the head of the police union in February 2018.

At present, domestic cultivation commands the attention of the national government. Though the initial application costs have been high, the barriers to entry may be removed as domestic groups continue to oppose preference for international partnerships.



Population
82.2m

Source: Worldbank/
IMHE/EMCDDA



GDP (2017)
€3.1t



Total Healthcare Expenditure (2017)
€425.8b



Total Beauty & Well being
Expenditure (2017)
€13.6b



Alcohol Consumption
(litres per capita, aged 15+, per year)
10.6



Daily Tobacco Users (% of population)
22.3%



Cannabis Users (% adults aged 15-64)
6.1%



Ruling Government Party
**Coalition - Social
Democratic Party,
Christian Democratic
Union and Christian
Social Union**



Party Stance on Cannabis
**In favour of medical
legalisation but recre-
ational legalisation is
unlikely before 2022**





2. Regulatory Environment

		
<p>Medicinal Cannabis Legislation</p> <p>Consumption and cultivation is legal with special permission from the “Federal Institute for Drugs and Medical Devices”.</p>	<p>Recreational Cannabis Legislation</p> <p>Inconsistent. Possession is illegal. Although amounts up to 6 - 15 grams (depending on region) is tolerated.</p>	<p>Industrial Cannabis Legislation</p> <p>Hemp cultivation (<0.3% THC) has been legal since 1995.</p>

Since March 2017, medical cannabis has been legal in Germany. Previously, the law had only accepted applications from around 1,000 patients. However, as of March 2018, the number of applications to the health insurance companies rose to 13,000. The health insurance companies have to bear the costs of care for patients prescribed medical cannabis, and 60% of requests for reimbursement have been approved. Cannamedical Pharma, one of the leaders in supplying German patients, estimates that 30,000 patients will be served in 2018 with imports of 22,000 kg.

To meet increasing demand for medical cannabis, Germany is dependent on the import of medical cannabis from abroad. As the Federal Ministry of Health announced, eleven applicants have applied to the Federal Institute for Drugs and Medical Devices (BfArM) for an import permit for cannabis for medical purposes. In the period from September 2017 to March 2018, Germany imported 2100 kg of medical cannabis from abroad, the maximum allowed by the initial legislation.

However, according to the Ministry of Health, further applications are still being processed. Since September 2017, the existing import permit holders have applied to increase their annual quotas to 10,900 kg. Two additional applications with a total volume of 10,400 kg are also being processed. A prerequisite for the import is that the cannabis can be traced back to its original source, which must be a licensed medical producer under the exporting state's control. These laws are the result of an international treaty to prohibit production and supply of specific drugs (the 1961 Single Convention on Narcotic Drugs).

Furthermore, import applicants must also have permits for cannabis testing, nationwide official permits by the Medicines Act, the import permit, the wholesale license and the manufacturing authorisation. The importing company must appoint a narcotics officer who has sufficient expertise. This expertise can include a university degree in biology, chemistry, pharmacy or human/veterinary medicine, or vocational training as a wholesale pharmaceutical merchant.

Extensive security measures must be introduced and demonstrated by the importer, including storage in closets, safe rooms and electrical monitoring systems connected to the police. The products must also comply with the guidelines of good practice for the collection and cultivation of medicinal plants (Good Agricultural and Collection Practice, GACP). In addition, the cannabis must also comply with the provisions of the monograph “cannabis flowers” of the German Pharmacopeia and other relevant monographs. The Federal Opium Agency is responsible for the application process of the import licence.

With regard to further legislation, there is a well-established advocacy community in Germany, accompanied by a strong research environment. Though decriminalisation looks likely, a regulated market for adult use is unlikely to be achieved before 2022 (or until the next election).





3. Healthcare Analysis

Source: INCB

Total Healthcare Expenditure (€b)	Total Pharmaceutical Spending (€b)	Estimated Cannabis Requirement 2018 (grams)	Estimated Medical Cannabis Market Value 2018 (€m)	Approved Cannabis-based Products
425.8	60.7	5,000,000	19.1	Sativex Cannabidiol Cannabis oil Nabilone Dronabinol Cannabis flower

As of January 2017, public health insurers, which provide cover to 90% of the population, were required to cover cannabis medication (up to 5 oz. per month), making Germany one of the most valuable markets in Europe. The insurance scheme covers all cannabis treatments and does not specify which conditions are covered.

However, it is difficult for patients to obtain a medical cannabis prescription. Doctors must be willing to issue prescriptions, which is made more difficult as doctors are challenged by health insurers, particularly as insurers are required to pay for every prescription.

The German health fund looks for medications that improve the quality of life, but are wary of insuring pharmaceutical products in general. However if insurance companies are persuaded that cannabinoids

actually improve the quality of public health and it lowers their costs they could ultimately become the industry's strongest allies.

The approval rate of the top three insurers (AOK, TK and Barmer) is between 62-64% for medical cannabis patient applications. However, for patients without health insurance coverage medical cannabis in Germany can cost between €1,500 and €2,400 depending on the state of supplies. In addition pharmacies can charge around seven euros per gram in order to grind cannabis for medical use.

The government has prioritised funds for research and development into cannabis treatments for epilepsy, which is estimated to affect about 540,000 Germans.

4. Commercial Opportunities

Eleven licences were on offer in 2017 for national/international producers but more licences can be expected once the application process is reevaluated in late 2018. Germany is the largest regulated medical market in Europe so it leads the way in terms of actual market valuation. It is anticipated that medical cannabis will relax attitudes towards the plant in general which will eventually lead to a fully regulated recreational market.

There will be domestic cultivation in Germany. However, entry into that space can cost between €30 - €60 million for applicants as a result of the high application fees and strict requirements. These costs will remain high over the next 18 months at least, as supply deficits guarantee strong sales and high market prices for any successful applicant. In addition, applicants are required to show experience producing both federally legal cannabis and a product that is GMP certified.





So far, major Canadian and Dutch firms are dominating the cultivation opportunities through joint ventures with German firms such as Spektrum, Pedianos, Nuuvera and Cannamed. Delays in the licensing process have resulted in these same firms building cultivation and production facilities elsewhere in Europe. With a presence in Portugal and Denmark, German-Canadian partnerships will look to Italy and Greece next. From a market perspective, Germany is developing a serious portfolio of available products.

Despite this, there are opportunities for entrepreneurs in Germany. Lower cost producers from across the globe are

now targeting Germany with medical cannabis products, anticipating at least an 18 month supply deficit before domestic cultivation begins. Ancillary services such as transport, logistics, security and quality assurance will certainly be a necessity for the German market.

The German medical and insurance system is embracing digitalisation, and so innovation in the tech sector is also likely. The barrier to market entry is high though, and potential applicants will require an understanding and experience of IT security, banking, European privacy law and data protection.

 Germany	 Forecast Medical Cannabis Market Value 2028 (€b)	 Forecast Recreational Cannabis Market Value 2028 (€b)	 Forecast Industrial Cannabis Market Value 2028 (€m)	 Total 2028 (€b)
Primary Market	7.8	5.4	25.6	13.2
Secondary Market		3.2		3.2
Total	7.8	8.5*	25.6	16.4

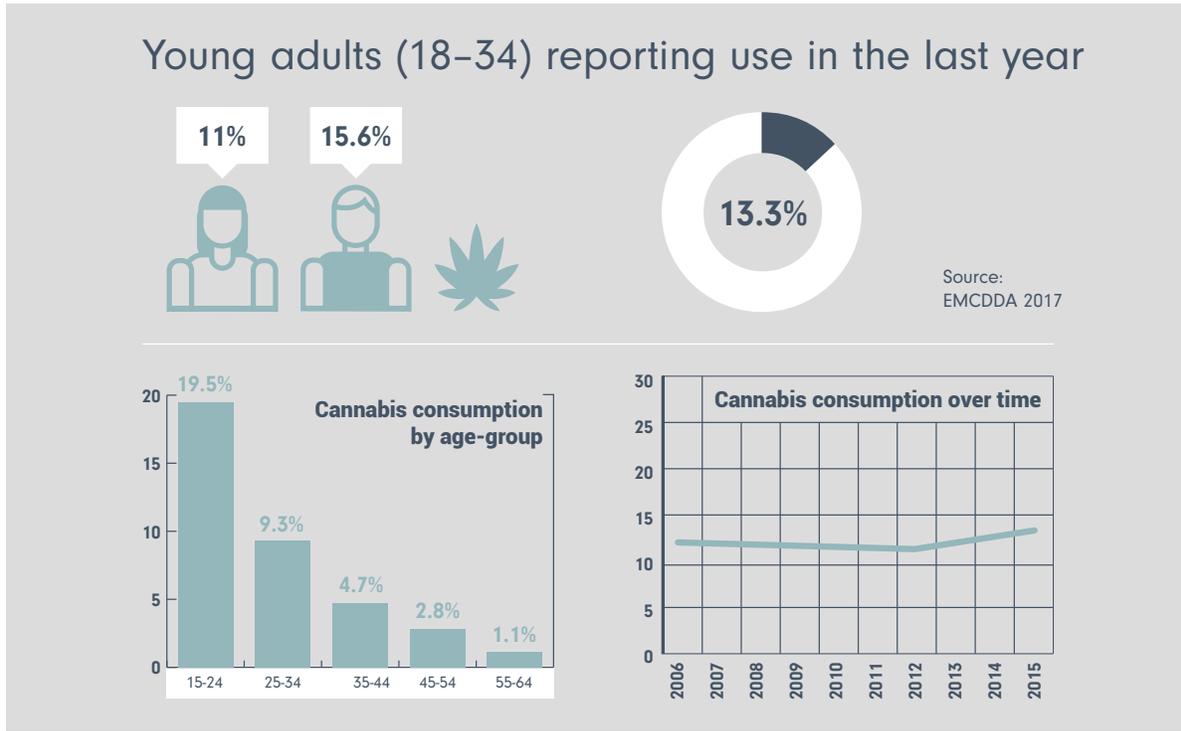
*may not sum due to rounding





5. Consumption

The below graph outlines the reported recreational cannabis use in Germany in 2017.



6. European Panel

Kai-Friedrich Niermann, Lawyer at KFN+

The cannabis agency within the Federal Institute for Drugs and Medical Devices (BfArM) is responsible for the production of medical cannabis domestically. It controls cultivation, harvesting, processing, quality inspection, storage packaging and delivery to wholesalers and pharmacists or manufacturers. After harvest is completed, the distribution falls under the jurisdiction of the respective growers and the other contracted companies.

Cultivation will be performed by the companies that are selected in a Europe-wide tender procedure and commissioned by the cannabis agency. The first tender procedure, whose deadline expired in June 2017, provided licences for the cultivation of a total of 6,600kg for the period 2019-2022. Since the applicants already had to

demonstrate solid experience in the manufacturing of medical cannabis, German companies were not eligible to bid. The court in Düsseldorf ruled that, on the basis of the previous tender, no cultivating licences could be granted. The ruling of the court affects all companies, both foreign and domestic. As a result of the decision, the whole tender process will be repeated, with new information to be issued by the BfArM soon. At the time of writing, no date is scheduled for the reevaluation but this new tender process will almost certainly not take place until late 2018.

Driven by a growing need for medical cannabis, demand is already exceeding the federal government’s original forecasts. Demand is expected to continue and will ultimately put pressure on the cannabis agency to reconfigure the tendering procedures in order to increase cultivation and imports.





In July 2017, The Greens introduced a bill, known as the Cannabis Control Law, to the German Federal Parliament proposing the legalisation of recreational cannabis. The law provided for a complete decriminalisation of users and a regulated market for cultivation, wholesale, retail, processing and import. During the debates, the Free Democratic Party and the Left Party joined forces to create a pro-legalisation coalition.

However, the current ruling coalition does not support the issue though parts of the co-governing SPD has been

surprisingly open in the discussion around cannabis distribution. Several initiatives for the regulated distribution of cannabis have been proposed in the Bundestag but the government is yet to vote. Most recently the Federation of German Police has advocated for legalisation. It remains an exciting proposition, as the Grand Coalition has made significantly more progress than any previous government.

