



Germany and Europe – update on the medicinal Cannabis and CBD market

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Medicinal cannabis in Germany

- a growing market



Cannabis market development – statutory health insurance

- Continued solid market growth in Germany, both in sales and in the number of SHI prescriptions
- There is no valid data for the number of patients; estimates are 90,000 to 120,000 SHI patients
- The data below are health insurance data, in addition, about 120,000 self-pay prescriptions (especially flowers) are given out via private prescriptions
- A total of around 500,000 prescriptions can therefore be assumed for 2021

	Prognose 2021	2020	2019	2018
Umsatz in Euro	ca. 190 Mio.	165,26 Mio.	123 Mio.	74 Mio.
<div><div>+ 15 %</div><div>+ 34 %</div><div>+ 67 %</div></div>				
GKV-Verordnungen	ca. 380.000	340.165	267.348	185.370
<div><div>+ 12 %</div><div>+ 27 %</div><div>+ 44 %</div></div>				

Quelle: GKV Spitzenverband; https://www.gkv-gamsi.de/media/dokumente/quartalsberichte/2021/q3_25/Bundesbericht_GAmSi_202109_konsolidiert_Sonderbeilage_Cannabis.pdf

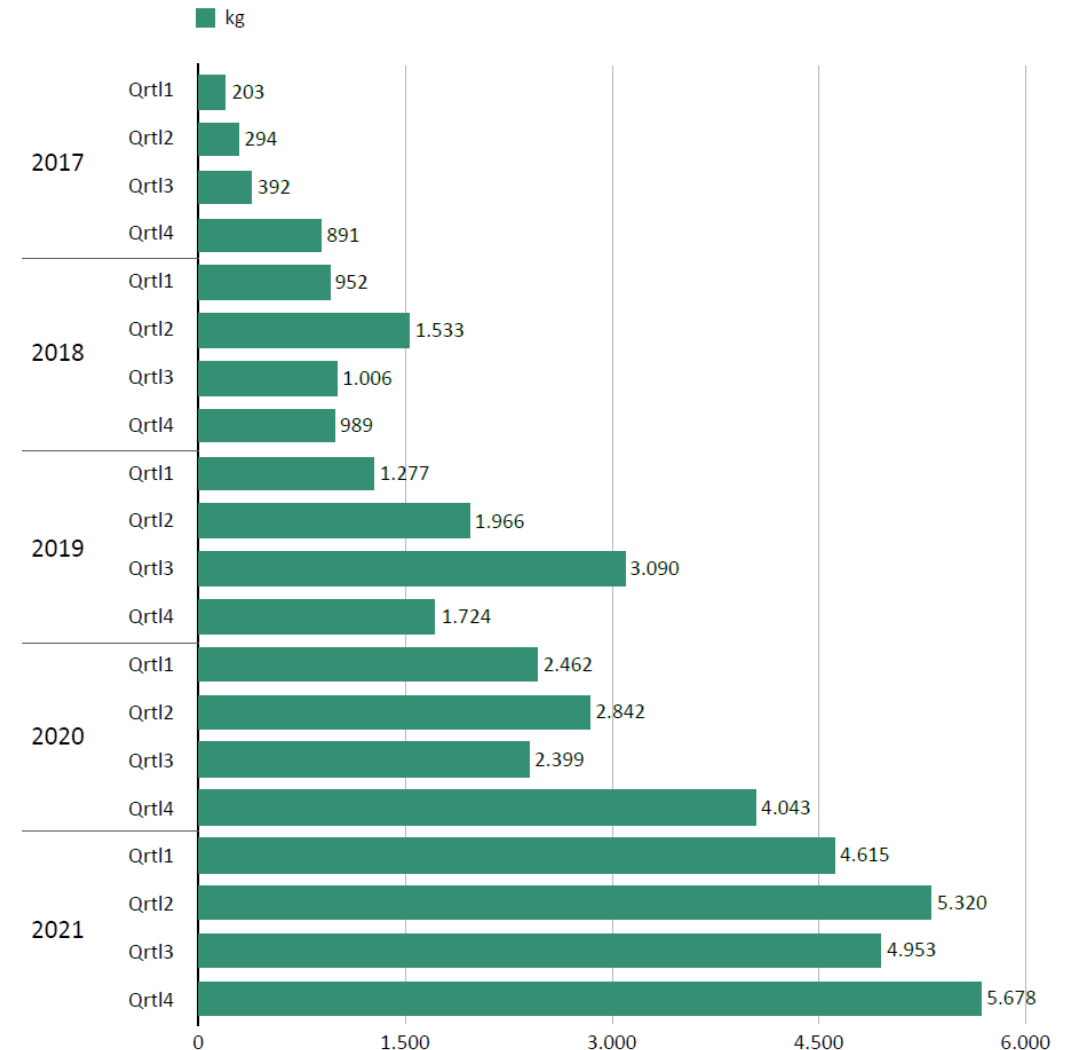
Market: Import Cannabis Flowers



- Total of 88 suppliers/wholesalers/importers in the market (Dec. 2021)
- Top 10 account for approx. 90% of sales, 66 suppliers with sales below EUR 500,000 (40 suppliers below EUR 100,000) in the full year 2021
- With Stadapharma, Neuraxpharm and Dermapharm as well as Dr. Reddy's/Betapharm there are now four established pharma players with generics expertise (rebate contracts/tenders) in the cannabis prescription drug market
- 2021 first open house rebate contracts for flower and full spectrum extract with rebates between 23 % and 30 %

Market: Import Cannabis Flowers

- Germany imported **20,4 tons** of medical cannabis flower, primarily for pharmacy dispensing in 2021
- German imports experienced a **sharp increase** in the **2021**
- **Caveat:** Massive oversupply situation



Evaluation after 5 years: On the sunny side of things

Patients benefit

Seriously ill patients have been able to obtain cannabis on prescription on a regular basis and get the costs reimbursed

Professional discussions and destigmatisation

Acceptance by physicians and pharmacists has risen sharply, especially in the last two years. Cannabis has been a perennial topic at pain management symposia over the past few years. Cannabis enters practice recommendations and guidelines.

More product variety and no supply bottlenecks despite Corona

The variety of products is becoming more and more extensive (> 130 varieties) and new dosage forms based on formulations are also becoming established

Review: Challenges remain

- Still about 1/3 of reimbursement applications are rejected by public health insurances
- The use of medicinal cannabis is limited to last line treatment (opioids before cannabis)
- Discount contracts ("Rabattverträge") by health insurances might have a negative influence on the development of this fairly new industry
- No harmonization of legal framework in Germany, regulatory ambiguities and regional differences
- The mandatory medical cannabis survey has missed its purpose: The data collection by BfArM does provide any information or guidance on the evidence based use of medicinal cannabis.

CBD Market in Europe



General: Market

- European hemp CBD players are facing huge challenges right now:

CBD raw materials from North/South America, China flooded the B2B market with questionable quality, no traceability, no certifications or production standards, and extreme low prices

- Bad business decisions and hype lead to this massive oversupply which led to massive price

Result

Commodification of an ingredient that had all the spectacle around it



General: Market

- Too many companies entering the same space, all making the same claims made CBD turn into a commodity ingredient that lost the ability to move into brand level for a lot of companies
- The fact that it was sold everywhere in gasstations, kiosk, book stores did not make it look exclusive
- People did not necessarily experience the promised benefits that were claimed and those promises were pretty big.
- CBD became a backup singer and is now just one ingredient in a list



Question: Will CBD come back as the star it once was ?

The problem: SC based differentiation between flowers and leaves

Draft non paper on cannabis derived ingredients in cosmetics:

“However, flowers (and leaves with tops) for which the resin has not been extracted,
they qualify as ‘drugs’, **except if they are coming from cannabis plant varieties with low levels of psychotropic substances and are legally cultivated in the Union**”

DRAFT NON-PAPER

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THE PURPOSE OF THIS DRAFT INFORMAL DOCUMENT IS TO SERVE AS BASIS FOR DISCUSSION BETWEEN THE EUROPEAN COMMISSION AND THE MEMBERS OF THE WORKING GROUP ON COSMETIC PRODUCTS

IT HAS BEEN PREPARED BY STAFF OF DG GROW WITH THE AIM OF PROVIDING PRELIMINARY VIEWS AND FURTHER EXPLANATIONS ON THE IMPLICATIONS OF THE CJEU JUDGEMENT CASE C-663/18 ON THE COSMETICS SECTOR

THIS DRAFT DOES NOT REPRESENT THE FORMAL POSITION OF THE EUROPEAN COMMISSION AND IT IS NOT BINDING IN ANY WAY.

IT WILL BE FURTHER ELABORATED BY THE COMMISSION SERVICES

Spotlight: Poland

EUROPE, FOOD & DRINK, LEGAL, NEWS, REGULATORY

Polish high court rules against health officials, clearing hemp flowers as food

The case:

- In 2019, the polish FSA withdrew a hemp food product from the market sold by the company Kombinat Konopny. The reason given: these hemp capsules have not obtained novel food authorization.
- Polish High Court affirmed that flower-based extracts such as CBD fall under EU food safety rules, however the interpretation of those rules was flawed regarding plant tops in their raw state and cited the agency for gross procedural errors



Spotlight: Germany

April 2022: “CBD drops are pharmaceutical products”

- The Administrative Court in Cologne ruled that the legal classification of CBD drops are medical products and must be approved by BfArM
- The court’s logic: The nutritional value of CBD is still an unknown. The plaintiff company could not prove that CBD might be used as a part of a diet rather than medical regime.
- The plaintiff’s suggestion that hemp tea might serve as one example was dismissed as the court maintained that cannabis tea is subject to narcotics law.



Recreational Cannabis in Germany

- Good news: The legalization of cannabis is progressing with great strides
- Germany is stepping into the 21st century when it comes to drug policy on cannabis.
The pledge to legalize cannabis was outlined in last year's coalition deal of Chancellor Olaf Scholz's government, aiming to have a legislative proposal in fall
- Burkhard Blienert, the Federal Government Commissioner for Addiction and Drug Issues, announced that he will start a "modern cannabis policy" in the country
- The Health Ministry that it will start holding expert hearings , more than 200 representatives from the medical, legal and other fields will take part, along with officials from various levels of government as well as international experts



Thank you for your attention!

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