GERMANY

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

The answers refer to Germany.

II. Legislation

2. Please provide links to applicable statutes and regulations.

Medical cannabis

- German Narcotics Act ("Betäubungsmittelgesetz", "BtMG")
- German Medicines Act ("Arzneimittelgesetz", "AMG")
- Volume V of the Social Insurance Code ("Fünftes Buch Sozialgesetzbuch", "SGB V")

Food (supplements)

- Regulation (EU) 2015/2283 on novel foods
- Novel Food Catalogue

Cosmetics

- Regulation (EC) 1223/2009 on cosmetic products

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

No.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

No.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

Since March 2017 the laws in connection with (medical) cannabis are pretty well settled.

III. General information (e.g., governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

Medical cannabis

The German Federal Institute for Drugs and Medical Devices ("Bundesinstitut für Arzneimittel und Medizinprodukte", "BfArM") is responsible (1) for the issuing of licenses to cultivate, produce, trade, import, export, deliver, sell or buy narcotics ("narcotics license"; Section 3 BtMG) and (2) for the tender process regarding the cultivation of cannabis.

An import authorization for medical cannabis (Section 72 AMG) must be granted by the competent authority of the state in which the importer´s company is located. The manufacturing permit (Section 13 of the German Medicines Act) and the wholesale permit regarding medicinal products (Section 52a AMG) is issued by the competent authority of the state in which the business premises are located.

Food (supplements) and cosmetics

The competent authority of the state in which the importer's company is located is also responsible for the monitoring of consumer products such as cosmetics and food (supplements).

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

In Germany, only cannabis for medical purposes is legalized, not for recreational use. However, the Berlin state government is currently discussing a pilot project to allow the provision of recreational cannabis to adults under certain circumstances.

Provided that a respective license from the BfArM has been obtained, cultivating, producing, trading, importing, exporting, delivering, selling, marketing and buying is permitted under German Law (Section 3 of the German Narcotics Act).

However, the cultivation of medical cannabis in Germany is subject to a public tender process. Only the companies who won the public tender process are entitled to cultivate medical cannabis in Germany.

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

In Germany, cannabis flowers and extracts are available for medical purposes. It is recommended by the BfArM to inhale cannabis via special vaporizers.

Furthermore, finished medicinal products with THC and/or CBD are available for medical use.

Products with CBD are offered in various forms: cosmetics, food, food supplements and others. The THC-content in these products must be below 0.2%. However, the legal status of these products is unclear at the moment /please see below under no 17.

A. Are the rules different for medical vs. adult recreational use?

Recreational use is not permitted.

B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

Medical cannabis (in the form of dried blossoms, extracts and finished medicinal products) can only be sold in pharmacies.

Products with CBS and a THC content under 0.2% do not fall under the German Narcotics Act and do not have to be sold in pharmacies.

C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

No.

7. What import and export is allowed in your jurisdiction?

The import and export of (medical) cannabis requires a narcotic license (Section 3 BtMG). In addition, the import of medical cannabis requires an import authorization (Section 72 AMG).

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

Prior to importing medical cannabis, the importer has to verify that the cannabis originates from a cultivation under state control in accordance with the UN Convention. According to the German Narcotics Act, only such cannabis can be imported into Germany that has a recognized medical purpose in the country of origin and is subject to control in accordance with the aforementioned requirements under international law; in particular, a national opium agency as outlined in the UN Convention (like the Cannabis Agency in Germany) has to exist in the country of origin.

Currently only medical cannabis from Canada and the Netherlands is imported to Germany on regularly basis. First licenses were issued to Uruguay, Colombia and Denmark.

B. Please describe restrictions on the import of cannabis seeds.

Cannabis seeds are excluded from the German Narcotics Act unless they are intended for unauthorized/illicit cultivation (see Annex I BtMG). Thus, there are no restrictions on the import of cannabis seeds.

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

A. If so, what distinctions exist?

B. If so, briefly describe the differences.

C. Identify any related laws that should be considered when answering this question.

The German Narcotics Act distinguishes between

- cannabis;
- medical cannabis;
- seeds;
- plants and parts of plants that
  - come from a cultivation in EU countries of certified seed, or
  - whose THC content does not exceed 0.2 % and if the trade with them is exclusively for commercial or scientific purposes which exclude any misuse for intoxication purposes (not including cultivation);
- industrial hemp.

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

CBD as such is not subject to the German Narcotics Act unless the possible THC traces do not exceed 0.2%.

However, regarding CBD products in food (supplements), the German Food Law has to be respected, in particular the European regulations on Novel Foods. For CBD in cosmetics, the European Regulation on Cosmetic Products (No 1223/2009) does apply.

IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

Under Section 31 (6) SGB V, persons with a serious disease insured in the German Statutory Health Care Insurance (SHI) (approx. 90 % of the population) are entitled to obtain cannabis in the form of dried flowers or extracts of pharmaceutical-grade quality and to medicinal products containing the active ingredients dronabinol or nabilone if

1. a generally recognised treatment in accordance with the medical standard

(a) is not available or
(b) cannot be applied in individual cases according to the reasoned assessment of the treating physician, taking into account the expected side effects and the state of illness of the insured person,

2. there is a not entirely remote prospect of a noticeable positive effect on the course of the disease or on serious symptoms.

Private health care insurance funds reimburse the costs of medical cannabis on prescription according to the general rules, i.e. if it is required for an effective curable treatment.

11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

Medical cannabis can be prescribed by every licensed physician.

12. Are there patient registration or cardholder requirements?

No. However, the costs for prescribed medical cannabis are only reimbursed to patients insured in the SHI provided that the respective health insurance fund has given its approval before the first prescription. The approval of the SHI can only be denied in justified exceptional cases.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

Yes. Pursuant to Section 17 BtMG, the holder of a license shall be obliged to keep records regarding each receipt and each dispatch of narcotics. This however only applies for cannabis products which are subject to the German Narcotics Act (in particular products with an THC-content over 0.2%).

14. Are special taxes imposed? On what and when?

No.

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

There are special requirements regarding the advertising for narcotics. In general, it is forbidden to advertise narcotics. However, it is allowed to advertise medical cannabis towards physicians, dentists and vets.

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

No special requirements.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by under age/minors.
B. Impact on beer, wine and spirit sales.
C. Tax revenue.
D. Impact on crime, including drug and alcohol addiction.

The BfArM carries out a non-interventional study regarding the prescription of medicinal products which shall run until March 31, 2022. Each physician who prescribes medical cannabis is therefore obliged to provide the BfArM with the data required for the study in anonymous form.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

At present, the classification of CBD products in Germany is unclear. The BfArM generally considers CBD products as medicinal products assuming pharmacological effects. However, CBD products are also distributed as food, food supplements or cosmetic products in Germany. The compliance with German law of distributing the products as food or food supplements remains uncertain, especially in the light of the recent inclusion

of CBD in the Novel Food catalogue by the European Commission. Lately, local food authorities have issued orders against the distribution of CBD products as food or food supplements.

Furthermore, pursuant to the BfArM, the first German harvest of cannabis can be expected in the fourth quarter of 2020. However, experts doubt that the companies who won the tender process are ready to harvest cannabis by then. In addition, the amount which was awarded during the recent tender process seems already too little. It remains to be seen whether the BfArM will award new amounts any time soon or whether the need will be still covered by imports.

19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

The punishability with regard to narcotics is regulated in the Sections 29 et seq. BtMG. Section 29 (1) No. 1 BtMG for example states that a prison sentence of up to five years or a fine shall be imposed on anyone who illicitly cultivates, manufactures, trades in, without trading, imports, exports, sells, gives away, otherwise puts into circulation, acquires or otherwise procures narcotic drugs. Section 29 (1) No. 3 BtMG also makes the possession of narcotics punishable without having a written permission for the acquisition (e.g. a prescription). A prison sentence not less than five years shall be imposed on anyone who cultivates, manufactures, trades in, imports or exports narcotics in no small quantities without permission and acts as a member of a gang.

A. Does enforcement differ based on quantity?

Yes. In the case of illicitly trading, manufacturing or selling of narcotics in no small quantities or in the case of possessing narcotics in no small quantities without having obtained them on the basis of a licence, imprisonment cannot be less than a year (cf. Section 29a BtMG). However, the public prosecutor's office may waive prosecution if the offender cultivates, produces, imports, exports, transfers, acquires, otherwise procures or possesses narcotic drugs in small quantities for his own use only. However, the quantity of cannabis which is considered as small – whereas the amount of THC and not the gross quantity is decisive – differs from state to state in Germany.

B. Does enforcement differ based on product type?

Enforcement does not differ based on the product type in which the cannabis is entailed (e.g. if it is a joint or a hash brownie), rather, the amount of THC is decisive. As regards CBD products which are sold as food (supplements) with a low THC amount (less than 0.2 %), local food authorities can also act on the basis of food law due to the inclusion of CBD in the Novel Food Catalogue. This issue does not exist regarding CBD products distributed e.g. as cosmetic products.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

TW: Taylor Wessing has demonstrated its interest in the thriving cannabis sector by creating a Cannabis Working Group consisting of experts whose expertise are of special relevance for the cannabis industry hereby following its principle to act as a "one stop shop" for firms. Combining the knowledge and experience of its experts in such areas as M&A, finance, tax, employment, trademarks and regulatory law, Taylor Wessing has advised U.S. and Canadian investors in connection with an investment into a German pharmaceutical wholesaler for medical cannabis and on setting up a business in Germany with the purpose of import and wholesale of medical cannabis in the past. Further, Taylor Wessing has advised leading Canadian growers and suppliers of medical cannabis on setting up a subsidiary in Germany as well as on participating in the tender procedure of the German Federal Institute for Drugs and Medical Devices (BfArM) for the "Cultivation, processing, storage, packaging and delivery of cannabis for medical use". In addition, Taylor Wessing has also advised CBD-products manufacturers and distributors in disputes with regulatory authorities concerning sale and marketing of CBD-products. Taylor Wessing has won the award for best law firm 2019 for pharmaceutical law due to its expertise in the life sciences sector (awarded by Handelsblatt in cooperation with Best Lawyers).

CMS: CMS has put a special focus on the growing cannabis business. To merge the expertise in the cannabis sector within CMS worldwide, CMS has founded a "Cannabis Initiative" within its long existing Lifesciences & Healthcare Sector Group. In this initiative, CMS lawyers from all relevant practice areas connect to discuss and advise on the pressing topics for the cannabis industry. CMS has been active in the sector for more than three years. In Germany, we have in particular advised Canadian and US-based companies in relation the BfArM tender process for cultivation licenses and have been instructed by both investors and private companies in M&A transactions in the sector. Moreover, we regularly advise clients on regulatory and advertising rules for medical cannabis as well as food and cosmetics with CBD. In 2018, CMS has been awarded the JUVE Law Firm of the Year Award for Pharmaceuticals & Healthcare with specific reference to our activities in the Cannabis sector.

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

- Blog article of Dr. Susanne Pech: Medizinisches Cannabis zukünftig auf Rezept ("Medical cannabis on prescription in future")
- Article of Dr. Jörn Witt und Dr. Susanne Pech in the Online-Magazine Gründerszene: Was Gründer von Cannabis-Startups in Deutschland wissen müssen ("What founders of cannabis start-ups in Germany need to know")

A. Are there any relevant trade organizations?

B. Are there any relevant lobbying organizations?

https://hanfverband.de/

C. Attorneys

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