Cannabis for medicinal and recreational purposes and new psychoactive substances – Critical review of recent legal initiatives in Germany

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List of Abbreviations

ABDA	Federal Union of German Associations of Pharmacists (Bundesvereinigung Deutscher Apothekerverbände)
Abs.	Absatz
AkdÄ, Akdae	Arzneimittelkommission der deutschen Ärzteschaft
AMG	German Drug Act (Arzneimittelgesetz)
BfArM	Federal Institute for Drugs and Medical Devices
BLE	Federal Office for Agriculture and Food (Bundesanstalt für Landwirtschaft und Ernährung)
BAK	Federal Chamber of pharmacists
BtMG	German Narcotic Drugs Act (Betäubungsmittelgesetz, Gesetz über den Verkehr mit Betäubungsmitteln)
BtMVV	Narcotic Drugs Prescription Ordinance (Betäubungsmittel-Verschreibungsverordnung)
BtM	Betäubungsmittel, Narcotic Drug
BtMKostV	Ordinance on Charges (Betäubungsmittel-Kostenverordnung)
BtMÄndV	Amendment of the regulation on Narcotic Drugs
CBD	Cannabidiol
DAB	German Pharmacopoeia (Deutsches Arzneimittelbuch)
DAC	German pharmaceutical Codex
EMA	European Medicines Agency EMA
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
Eurojust	Agency of the European Union, situated in the Hague, dealing with judicial co-operation in criminal matters. The seat of Eurojust is.
Europol	European Police Office, situated in the Hague, the law enforcement agency of the European Union
GÜG	Precursor Monitoring Act (Grundstoffüberwachungsgesetz)
GÜGKostV	The Ordinance on Charges serves to cover the costs that arise for the BfArM through official acts in the field of precursor control
HAB	German Homeopathic Pharmacopoeia
LEAP	Law Enforcement Against Prohibition Deutschland
MDMA	3,4-Methylendioxy-N-methylamphetamin, Ecstacy
NKR	National Regulatory Control Council (Nationaler Normenkonntrollrat)
NFP	National focal point, NFPs participate in the Early warning system and report to the EMCDDA
NPS	new psychoactive substances
NRF	New Prescription Formulatory
OMC	Dutch Office of Medicinal Cannabis (Bureau voor Medicinale Cannabis,)

§	paragraph
REITOX	‘Réseau Européen d´Information sur les Drogues et les Toxicomanies (European information network on drugs and drug addiction)
SmPC	Summary of product characteristics
StGB	Criminal Code (Strafgesetzbuch)
StVG	Road Traffic Act (Strassenverkehrsgesetz)
THC	Tetrahydrocannabinol
UNGASS	UN General Assembly Special Session
USP	United States Pharmacopeia

1 Introduction

"EU citizens spend more than 24 billion Euros every year on illegal drugs including cannabis and heroin" a citation from Alexis Goosdeel, head of EMCDDA, European Monitoring Centre for Drugs and Drug Addiction (Reuters, 2016) while introducing the annual European Drug Report 2016 in Brussels. According to this drug report (EMCDDA European Drug Report, 2016), cannabis accounts for the largest share in value of Europe's illicit drug market. Over one million seizures of illicit drugs are reported annually in Europe. Cannabis is the most commonly seized drug, accounting for more than three quarters of seizures in Europe (78 %), cocaine ranks second overall (9 %), followed by amphetamines (5 %), heroin (4 %) and MDMA (Ecstasy 2 %).

Addictive substances and behaviors cause health, social and economic problems in Germany. According to National Strategy on Drug and Addiction Policy (Government, 2012) elaborated on the initiative of the former Federal Government's Drug Commissioner, Mechthild Dyckmans, 16 million people smoke, 1.3 million people are addicted to alcohol, and 1.4 million people are addicted to prescription drugs and 600,000 people exhibit problematic cannabis consumption, and 220,000 people are addicted to cannabis.

Recent survey data indicate that purity and/or potency of illicit substances is increasing (EMCDDA European Drug Report, 2016). New emerging psychoactive substances are more and more entering the German market and at the same time the consumption of cannabis is rising. A growing concern is that the production of cannabis and synthetic psychoactive substances now takes place within Europe, closer to consumer markets.

German society is confronted with an aggravating drug problem and the call for a more efficient drug policy is getting louder- and - the awareness that decades of prohibition did not show the desired success is growing.

At the same time we face a revived appreciation for and interest in cannabis based therapy. Medical and pharmaceutical experts are re-evaluating the medical benefit of cannabis, including herbal preparations, dried plant parts and authorized medicinal products, with the focus on patients with a chronic and severe illness.

German policymakers tackle the situation with three new drafted laws:

- **Legalization of cannabis for medicinal purposes: Bill 2016/0014/D, amending the narcotics regulations and other provisions**
- **Legalization of cannabis for recreational purposes: The Cannabis Control Act**
- **An act combating the dissemination of new psychoactive substances: New Psychoactive Substances Act**

The legislative activities revived ongoing discussions encompassing social, legal, regulatory, medicinal and pharmaceutical aspects.

Cannabis for medicinal purposes

Cannabis sativa has been used for centuries as a remedy. The medical application of cannabis plant parts and preparations is supported by records from China and India more than 2,000 years ago. Ancient texts from cultures in Africa but also in Europe (e.g. Greece and the Roman Empire) describe the use of cannabis to treat diseases. Cannabis extracts were listed in the British, and later in the US Pharmacopeia (1850), for sedative and anticonvulsant effects (Kalant, 2016). The disadvantages of an herbal remedy, like variable composition of plant preparations, short shelf-life, inaccurate dosage resulting from

unpredictable Delta(9)-Tetrahydrocannabinol content, the main source of the pharmacological effects, were detected early (Madras, 2016). The decline of medicinal cannabis was accelerated by the development of morphine, aspirin, and other opium-based medicinal products (Eddy, 2010). The risks of abuse and intoxication but also economic interests as well as the spirit of that time led to the Marihuana Tax Act, initiated by Harry Anslinger, the US Commissioner of the Federal Bureau of Narcotics in 1937. Subsequent restrictive laws prohibiting the growth, possession and consumption of cannabis were passed worldwide.

The movement to revive cannabis as a medicine to alleviate pain, seizure disorders and enhance appetite, to name only a few, is driven by multiple factors. There is the prospect to help patients with debilitating chronic diseases, including Multiple Sclerosis, Crohn's disease, Alzheimer's disease, cancer (Franjo Grotenhermen, 2012), and there is the justified hope that the relaxing, pain relieving and antidepressant effects of cannabis could benefit patients in palliative care.

On January 8th 2016 Federal Health Ministry of Germany presented a drafted bill amending the narcotics regulations with the purpose to enable the marketing and prescription of pharmaceutical-grade cannabis to specific, particularly chronically and seriously ill patients. It postulates controlled access to pharmaceutical-grade cannabis dispensed by pharmacists. To ensure the quality-assured supply of medicinal cannabis, the cultivation of cannabis for exclusively medicinal purposes shall be allowed in Germany. The Federal Institute for Drugs and Medical Devices (BfArM) will be assigned as competent authority, in charge of the control of the cultivation of medical cannabis (state agency).

Shift of paradigm in drug policy - Cannabis for recreational purposes

Narcotic drug policies in the European Union are one of the most controversial subjects and the call for other approaches than mere prohibition is getting louder. The legal status of cannabis for personal use is a demanding issue.

Cannabis has become the most abused illicit substance in Europe. For most (adult!) individuals, recreational cannabis use (not excessive or abuse) does not present a significant hazard to health. Under the influence of the inhaled drug, most consumers experience easing, mild euphoria and change in perception, such as intensification of taste, sound or physical contact. For young people, yet not as harmless as for adults, test of courage and curiosity prevails (European Commission, 2016) as reason for consumption. There is no point denying that for a certain percentage of drug users the relaxing effects of cannabis convert into a constant need until addiction, interfering with intellectual development, as well as interpersonal and occupational advancement (Madras, 2016). Overdose related adverse effects are anxiety and panic attacks, increased heart rate (Grotenhermen, 2003) but fatal intoxications have not been verified. It is discussed if cannabis is really so dangerous that justifies the same scheduling as e.g. Heroin. In a recent rating study evaluating drug harms performed by EU drug experts, alcohol, heroin and crack (most addictive form of cocaine) emerged as the most harmful drugs, whereas other drugs including cannabis displayed comparatively low values, making it much less harmful than alcohol (Jan van Amsterdam D. N., 2015). Studies from Lachmeier and Rehm confirmed that the danger of cannabis use is considerably overestimated (Lachenmeier, D. & Rehm J., 2015).

The consumption of cannabis, as such, is not illegal in Germany, but its acquisition, possession and cultivation is illegal. This leads to criminalization of drug users, a legal inconsistency and injustice for the individual. The impact of illegitimate drug trade on society, including illicit drug trafficking, acquisitive crime or violence and money laundering is another critical point addressed in new legislative strategies. Last but not least, decades of prohibition did not show desired success, and it is a given fact

that narcotic drugs including cannabis are easily available and that black market trade is thriving (EMCDDA European Drug Report, 2016).

The drafted Cannabis Control Act, aiming at legalization of natural cannabis for recreational purposes, has been introduced by Bündnis 90/ The Green party in the year 2015. This bill focusses on protection of consumers and minors by establishing a regulated, quality controlled cannabis retail system. The drafted Cannabis Control Act includes inter alia provisions for consumption, private cultivation, retail, wholesale, tax and import of cannabis. The special retail concept of this bill specifies that cannabis is freely available for adults in specialized cannabis shops.

Cannabis and Cannabinoid substances are present in the German society: Cannabis for medicinal and recreational purposes and synthetic cannabinoids. The debate concerning the risk that pose new psychoactive substances and cannabis, to public health and their illegal trade, currently an inseparable part of the discussions, is ongoing. Yet, in contrast to legalization initiatives for medicinal cannabis or decriminalization strategies for its recreational use, there is general consensus that new psychoactive substances (NPS) are harmful and that this growing problem requires special and intensified attention (chapter 7).

New Psychoactive Substances Act – a new approach to ban the rapidly emerging psychoactive substances

The dynamic and constantly changing market for new drugs poses a growing risk to European population (EMCDDA European Drug Report, 2016). Limited information is available on the use of new psychoactive substances, but the 50 000 reported seizures of these drugs in 2014 provide some insight on how severe this problem is. In 2014, 101 new psychoactive substances were reported in the EU for the first time, compared with 41 in 2010. More than 450 substances are currently being monitored by the EMCDDA.

The consumption and supply of new psychoactive substances (NPS) have spread rapidly in Germany (as in other EU Member States) in recent years. The new substances or “designer drugs”, "legal highs", “bath salts” are often sold via the Internet and are advertised with aggressive and sophisticated marketing strategies. They are analogues or chemical derivatives of controlled psychoactive substances designed to produce effects similar to the substances they mimic.

A legal loophole: The substances are typically analogues of compounds prohibited under current drug laws, in Germany the Narcotic Drug Act (Betäubungsmittelgesetz BtMG). Yet they differ slightly from already scheduled drugs and are thus circumventing narcotic regulations. That means that these substances are legal, because they have not yet been classified under the respective regulations: either because they have not been detected and identified up to now or the procedure to classify them under the narcotic drug act is ongoing. The legal status for most of these substances can be best explained as – “not yet forbidden…“ at least, not yet classified.

New psychoactive substances emerge on the market in an unprecedented growth in number and diversity, and the authorities are in a “race” trying to keep up with the chemists, who are designing new chemical compounds to bypass the legislative system. This situation makes it clear that there is an urgent need for a rapid and effective process to regulate these substances

The Federal cabinet has passed a new bill on 4th May 2016 banning new psychoactive substances: The New Psychoactive Substances Act (NpSG). The ban includes trading, placement on the market, manufacturing, importing, exporting and transit, acquisition, ownership and the administering of NPS. Two groups of substances of NPS are subject to the ban: compounds derived from 2-phenylethylamine

(including cathinones) and Cannabimimetic agents / synthetic cannabinoids. The substances classified under the new act are defined according to a modular system. This new legislative approach manages to capture analogues or chemical derivatives of scheduled compounds and not only individual substances - a lead in the race?

2 Current legal status in Germany: BtMG - Narcotics Drug Act

In Germany the Narcotics Drug Act (BtMG) was adopted in 1971. It was based on the Single Convention on Narcotic Drugs of 1961 as well as on the draft of the Convention of 1971 on Psychotropic Substances (United Nations, 2016).

The development of the drug situation in Germany led to initiatives of members of the German Bundestag and the Federal Government (EMCDDA, Country legal profiles provided by the EMCDDA, 2016).They resulted in complete revision of the narcotics law. The "Act to Regulate the Trade in Narcotics" (Narcotics Drug Act – BtMG (BfArM, 2016) was passed by the German Bundestag on 28th July 1981 and entered into force on 1st January 1982. It is the central German law governing narcotics. The BtMG includes the following provisions:

- Definitions of narcotic drugs and list of all narcotics in annex I - III
- Legal manufacture, trade and operations as well as licensing procedures and obligations in the context of the trade in narcotic drugs
- Medical prescription of narcotics including labelling and advertising
- Handling and security measures
- Protection of juveniles and adolescents
- Criminal and administrative offences
- Alternative measures for drug-addicted offenders
- Cultivation of commercial hemp
- Provisions for other authorities including Federal Armed Forces, Police and Civil Defence
- Notifications and information including annual report to the United Nations

Definiton of "narcotic drugs" Narcotic drugs ("Betäubungsmittel", BtM) are defined and regulated by the German Narcotic Drugs Act ("Betäubungsmittelgesetz", BtMG). The BtMG includes annex I, II, III that list substances and preparations, thus putting them under the auspice of the act. The decision to include a substance or preparation in these schedules is based on its mode of action, its potential to cause dependence or its direct or indirect danger to public or individual health as well as if this substance/preparation can act as a precursor for a narcotic drug. Substances and preparations are also subject to the BtMG if required by the schedules of the Single Convention on Narcotic Drugs of 1961 (United Nations, 2016) or the Convention of 1971 on Psychotropic Substances (United Nations, 2016)

Information panel 1 Definition of "narcotic drugs" and "substance" according to German BtMG

Narcotic drugs as defined by the German Narcotic Drugs Act (BtMG) are the substances and preparations listed in annex I to III of that Act.

Definition of "narcotic drugs " according to German BtMG:

§ 1 of the German BtMG defines : " …, narcotic drugs means the substances and preparations listed in Annexes I to III."

These annexes are regularly reviewed and updated in an amendment process, Amending Regulation on Narcotic Drugs (Betäubungsmittelrechts-Änderungsverordnung (BtMÄndV). Additionally subsection 4 of §1 BtMG refers to the International Narcotics Conventions (United Nations, 2016) in their respective versions as binding for the Federal Republic of Germany.

Definition of "Substance" according to German § 2 BtMG:

a) Chemical elements and chemical compounds as well as their naturally occurring mixtures and solutions,
b) Plants, algae, fungi and lichens as well as their parts and components in a processed or unprocessed state,
c) Bodies of animals, also live animals, as well as human and animal body parts, components and metabolites in a processed or unprocessed state,
d) Microorganisms including viruses as well as their components or metabolites;

Definition of "**preparations**" according to German BtMG: without regard to its aggregate state, a mixture of substances or the solution of one or several substances except the natural mixtures and solutions.

2.1 Annexes of the BtMG

A substance or preparation is included in these annexes if scientifically justified based on its mode of action (see chapter above):

Annex I: Controlled drugs not eligible for trade, nor for medical prescription.

- With exceptional license of the BfArM substances can be used for "scientific and other purposes of public interest".
- That applies e.g. to heroin, LSD, MDMA, Methylendioxy-N-methylamphetamin = Ecstasy, mescaline and **cannabis** (marijuana, plant and plant parts) with the following **exemptions**: cannabis for pharmaceutical preparations and if ingredient in an authorized medicinal product, **as specified in annex II and III and cannabis seeds** (under certain conditions and if used for agricultural purposes) (Gesetze-im-internet: Betäubungsmittelgesetz und Anlagen I bis III, 2016)

Annex II: Controlled drugs eligible for trade but not for medical prescription.

- Companies and pharmacies can acquire and manufacture Annex II substances but cannot hand them over to patients –they are often precursor substances for Annex III substances),
- That applies to: d-cocaine, isocodeine, isomethadone, dexamphetamine and **cannabis** (marijuana, plant and plant parts) if meant **for preparation of pharmaceutical formulations for medicinal purposes**

Annex III: Controlled drugs that are eligible for trade and may be prescribed.

- Prescription is only possible with a special narcotic prescription
- That applies to: codeine, buprenorphine, morphine, methadone Amphetamine, barbital, cocaine, codeine, nabilone, opium and **cannabis** (marijuana, plant and plant parts) **if ingredient in an authorized medicinal product or pharmaceutical formulation preparation**

2.2 Procedure to amend annexes of BtMG: the amending regulation on narcotic drugs (Betäubungsmittelrechts-Änderungsverordnung (BtMÄndV)

The annexes of the BtMG are amended regularly via ordinance of the federal government. The amendment of the annexes I to III is according to § 1 of the German BtMG organized as follows: *"... The Federal Government is authorized to amend or supplement, upon the hearing of experts by means of an ordinance adopted without the consent of the Bundesrat, Annexes I to III as is necessary" – "(1) on the basis of scientific knowledge because of the effect of a substance, especially in view of the creation of an addiction, (2) because of the possibility of producing narcotic drugs from a substance or by use of a substance or (3) for the security or control of the trade in narcotic drugs or other substances or preparations because of the extent of abuse and the indirect or direct danger to health.*" In urgent cases, however, the Federal Ministry of Health has the authority to include substances and preparations which are not medicinal products into the appropriate schedules for a period of one year if this is necessary due to the extent of misuse and the actual danger to health (BtMG § 1 subs. 3).

A legislative initiative is necessary for an amendment: the Amending Regulation on Narcotic Drugs (Betäubungsmittelrechts-Änderungsverordnung (BtMÄndV). The committee of independent experts (acc. to § 1 abs. 2 BtMG) advises the government and provides scientific recommendations regarding the addition or withdrawal of substances to the annexes of the BtMG. The committee meets upon request, normally twice a year and provides recommendations, yet, their advice is not legally binding.

The first BtMÄndV was published 8th August 1984 in the Federal Law Gazette (Federal Law Gazette Archive, 2016). Since then many amendments have been made and the most recent BtMÄndV, the 31st Ordinance amending provisions of narcotics legislation (31. BtMÄndV 2016/48/D) includes six new psychoactive substances to annex I and II BtMG 7.4.

2.3 Legal framework and consequences of the illegitimate consumption of intoxicants /narcotic drugs

In Germany, the consumption of narcotic drugs (not prescribed medicinal products) is not subject to sanctions. The purchase and possession are punishable, since they are associated with the danger of the further spread of drugs.

The German Narcotic Drugs Act is the legislative basis for narcotics offences. The German Regulation on the Prescription of Narcotic Drugs (Betäubungsmittel-Verschreibungsverordnung, BtMVV), the Precursors Monitoring Act (Grundstoffüberwachungsgesetz) and the German Drug Act (Arzneimittelgesetz, AMG) belong to the other legal provisions concerning drug related offences.

BtMG includes a comprehensive catalogue of criminal and administrative offences as well as additional provisions applicable in connection with the illicit trade in narcotics. The Narcotics Act distinguishes three categories of offences according to their sentencing range:

- Criminal offences punishable by up to five years imprisonment or a fine; § 29 abs. 1 BtMG
- Serious cases of criminal offences punishable by imprisonment of not less than one year and not more than 15 years; § 29 abs. 3 and § 29a BtMG
- Crimes which are punishable by imprisonment of not less than two years (in special cases: not less than three or five years) and not more than 15 years; § 30 to 30b BtMG.

The illicit trafficking and smuggling (import, export, transit), the illicit cultivation and manufacture of narcotic drugs rank among the most serious drug-related offences The classification mainly depends on the set of factual circumstances surrounding the offence, which are explicitly stated in the Act.

Aggravating circumstance are:

- **not insignificant quantities** of narcotic drugs, e.g. in connection with their import.
- for an adult to supply narcotics to a minor (§ 29a),
- for anyone trafficking narcotics "professionally" or as a member of a gang (§ 30, 30a)
- committing a serious drug-related offence, to carry a firearm or other articles which, by their nature, are likely and intended to cause bodily harm (§ 30a).

In contrast to the above discussed **circumstances** that have an impact on the seriousness of the offence, the German BtMG does not differentiate between different narcotic substances or ranks the danger to public health imposed **by individual drugs** (Point, 2016). The BtMG can be described as a regulatory and administrative law, regulating the trade, import, export and prescription of narcotic substances. Regulatory law breaches of the BtMG can be sanctioned by administrative fines of up to €25,000 (§ 32 BtMG Administrative offences). Possession of and dealing (especially trafficking) in narcotic drugs listed in the BtMG are classified as criminal offences according to §§ 29 - 30a of the BtMG.

The interpretation and methodological application of the rules of the BtMG adhere to the system of the German Criminal Code (Strafgesetzbuch, StGB) and the courts determine a hierarchy of drugs based on an empirically graded scale of “danger to public health” (Point, 2016).

2.3.1 Therapy instead of punishment

According to the provisions on "therapy instead of punishment" (§§ 35 to 38 BtMG) the enforcement authority (usually the public prosecutor) may, with the approval of the court, postpone the execution of a prison sentence or the remainder of a sentence in cases where the convicted person committed the offence as a result of their addiction to narcotics. Another prerequisite for this postponement is a participation in an addiction rehabilitation treatment.

Lorenz Böllinger, emeritus professor of the department of Law at the University of Bremen explains in his article from 2002 (Böllinger, 2002) in more detail: The option of a deferral of accusation or punishment exists since 1981 (§ 37 BtMG). A special decree for drug addicted offenders allows that the prosecutor in charge refrains from accusing by a preliminary decision based on the following conditions: the punishment must not exceed 2 years; there must be a good prognosis for rehabilitation, the perpetrator must already undergo some kind of drug treatment, the court that has passed the verdict must agree, and the perpetrator must regularly provide evidence of continuing treatment. The German StGB provides acc. to §56 “Power of court to suspend sentence” the option to defer the enforcement of imprisonment by up to 2 years to give drug addicted criminals the opportunity to undergo therapy.

Böllinger also addresses in his article that a mandated rehabilitation/detoxification treatment should not be misinterpreted as “recreation instead of punishment”. These treatment are not comfortable and can

be included in detention. The German law enforcement provides the option for a compulsory detoxification treatment to drug addicted offenders.

The German Criminal Code: compulsory detoxification treatment (Maßregelvollzug)

The German Criminal Code (Strafgesetzbuch, StGB (Law, 2016) addresses the consequences of the consumption of intoxicating substances. According to § 63 and § 64 StGB a compulsory placing of a drug addicted or mentally ill offender in a forensic psychiatric hospital can be imposed (Maßregelvollzug). § 64 StGB regulates, that if someone committed a crime in an intoxicated state or as a reason of his intoxicated state (applies to alcohol and all kind of drugs) and is convicted of an unlawful act the court shall order a placement in an institution for professional drug rehabilitation /detoxification.

2.3.2 Driving under the influence of intoxicants/drugs

Blood tests can be ordered if police suspects driving under the influence of intoxicants. After a suspect has been convicted the German legislation system provides two sanction approaches to punishment: the regulatory and the criminal offence.

- **Regulatory offence**: possible sanctions range from post bail, to fine proceedings up to 1,500 Euro, to a driving ban according to § 24a of the Road Traffic Act (Strassenverkehrsgesetz, StVG).
- **Criminal offence: i**f classified as a criminal offence, it is referred to the public prosecutor.

Driving under influence of intoxicants and/or alcohol is addressed in StGB in the section "Drunkenness in Traffic" §§ 315 - 316: A person that drives a vehicle in traffic and is not able to do so due to consumption of alcohol or other intoxicants can be punished with imprisonment up to one year (§ 316) or a fine if the act is not punishable under § 315a or 315c StGB. Section Endangering Road Traffic § 315c StGB regulates the breeches of law concerning traffic in more detail if the driver under drug influence endangered other persons or valuable property, the sentence may be increased by up to 5 years**.**

A temporary driving ban can be ordered by the criminal court and it is possible to withdraw the driving license with a blocking period. After a certain time a new driving license can be granted after the offender has successfully passed psychological / medical tests.

3 Current legal status for cannabis in Germany regarding possession, cultivation, consumption and cannabis based therapy

The lively debate amongst politicians, specialists and citizens on how to deal with cannabis from a social, political and criminal law perspective led to a general atmosphere of striving for reformation. Before addressing the current initiatives the status quo has to be analyzed. Chapter 3 outlines the legal frame work regarding narcotic drugs and intoxicants in Germany. All the above addressed legal requirements also apply to cannabis. In the following the special conditions and legal requirements for cannabis are explained.

Cannabis – German Narcotic drug Act

In Germany plants and parts of plants of the genus cannabis and Hashish, resin of the cannabis plants and the Tetrahydrocannabinols Δ6a(10a)-THC, Δ6a THC, Δ7-THC, THC-Δ8, Δ10-THC and their stereochemical variants in accordance with § 1 BtMG are classified as substances not eligible for trade,

nor for medical prescription – thus scheduled in annex I of BtMG (chapter 2.1. Without approval of the BfArM cultivation, production, trade, import, export, delivery, sale, other placing, acquisition and ownership by all parts of the plants of cannabis are punishable according to § 29 etc. BtMG. The active ingredient of cannabis tetrahydrocannabinol (THC-Δ9) is subject to the annex II of the BtMG.

Since May 2011 with the announcement of the 25th amendment of the regulation on Narcotic Drugs (25. BtMÄndV) it is legal to put cannabis on the market provided that it is used for the preparation of medicines. Cannabis based medicinal products with marketing authorization can since be prescribed (25. BtMÄndV; 11.05.2011 BGBl.).

3.1 Cultivation of cannabis

The attempt to cultivate cannabis is punishable and starts with purchasing of seeds and preparation of cultivation soil/substrate. The acquisition and possession of cannabis seeds is already punishable, if it is intended for illicit cultivation. The attempt is already illicit and punishable (§ 29 abs. 1 BtMG).

THAT MEANS that **the attempt to** grow the plants with respective THC content **has not to be successful to be considered as a criminal act!**

Industrial cannabis plants/ hemp and respective competent authorities and regulations

Plant fibers of flax or hemp for compound materials are used in the automotive industry and as insulation materials**.** Cannabis for medicinal or recreational purposes and industrial hemp are both members of the species *Cannabis sativa* and contain the psychoactive component tetrahydrocannabinol (THC), yet distinct strains used for industrial purposes have lower concentrations of THC.

Hemp cultivation has to be notified at the competent authority in Germany, the Federal Office for Agriculture and Food (BLE-Bundesanstalt für Landwirtschaft und Ernährung). BLE acts on behave of Federal Ministry of Food and Agriculture and is the German market-regulating agency for the common market organizations, within the European Union, for agricultural products including flax and hemp. The BLE monitors the import of seed material and the implementation of the laws and is for hemp the competent authority regarding licensing of industrial hemp varieties (Federal Office of Agriculture and Food, 2016), (Bayer. Min. Ernährung, Landwirtschaft u Forst, 2016).

Currently approx. 42 varieties of industrial cannabis are allowed to be cultivated in the EU according to the catalogue of varieties for agricultural plant species and are published in compliance with Directive 2002/53/EG (Common Catalogue of varieties of agricultural plant species, pursuant to Council Directive 2002/53/EC)

Influence of EU financial support system on quality of industrial hemp

Financial support is granted for certain arable crops, including flax and hemp. This support influences the quality and compliance in the EU considerably. If a producer of hemp for fibers wants to apply for this financial support the regulations have to be followed strictly (details explained below). Financial support acts in this way as an additional regulative or compliance tool.

According to the Commission Regulation (EC) No 2860/2000 (Commission Regulation (EC) No 2860/2000 of 27 December 2000 amending Regulation (EC) No 2316/1999 laying down detailed rules for the application of Council Regulation (EC) No 1251/1999 establishing a support system for producers of certain arable crops, including flax and hemp:

- Only varieties of flax and hemp are allowed that are listed in the Common Catalogue of Varieties of Agricultural Plant Species as fiber plants
- The tetrahydrocannabinol content of the authorized hemp varieties shall not exceed 0,2 %. list of eligible varieties should therefore be drawn up
- Mandatory use of certified seeds

Commission Regulation (EC) No 1529/2000 of 13 July 2000 establishing the list of varieties of *Cannabis sativa L.* eligible for aid under Council Regulation (EEC) No 2358/71. The authorized varieties of *Cannabis sativa L.* eligible for aid under Article 3(6) of Regulation (EEC) No 2358/71 are listed in Annex B to Regulation (EEC) No 1164/89.

3.2 Consumption of Cannabis

The consumption of narcotic drugs is not illegal in Germany. It can be considered as self-harm behavior that is not subject to punishment. Article 1 and 2 of the German constitutional law (Grundgesetz) grants every human autonomy to decide to compromise his own legal interests or even to hurt himself. The Narcotics Act describes in § 29, abs. 1 "criminal offences" the different forms of illegal action, such as the acquisition, possession or the cultivation but consumption is not listed.

This leaves consumers in a paradox situation: it is illegal to possess and to buy cannabis but the consumption is not illegal.

Drug consumption rooms

Drug consumption rooms acc. to BtMG (§ 10a) are entitled to provide drug users with sterile injecting equipment, counselling services, medical care and referral to addiction treatment services. Drug consumption rooms are primarily meant to reduce the acute risks for high-risk drug users like disease transmission through unhygienic injecting and drug-related overdose deaths. The 3rd amendment to the BtMG (3. BtMG-ÄndG) came into effect on 1 April 2000 and legalized the operation of drug consumption rooms. The BtMG leaves it to the discretion of the Federal Länder to permit drug consumption rooms. The Land government has to issue an ordinance based on the Narcotics Drug Act which regulates the details regarding the drug consumption rooms. The operators of drug consumption rooms have to co-operate closely with all competent authorities and institutions. They are obliged to:

- contact drug addicts as regularly as possible
- provide survival assistance
- prevent the typical inflectional diseases related to injecting drug use, such as HIV and hepatitis infections
- stabilize their health and offer them counselling and treatment to help them quit their illicit activities and drug addiction
- prevent illicit drug trafficking

The first supervised drug consumption room was opened in Switzerland in June 1986. According to the internet presentation of the EMCDDA status February 2016 there are 31 facilities in 25 cities in the Netherlands, **24 in 15 cities in Germany**, 12 in 3 cities in Spain, one in Norway and Luxembourg, five in Denmark and 12 in Switzerland. Three models of drug consumption rooms are operating in Europe: integrated, specialized and mobile facilities. The vast majority of drug consumption rooms are integrated in "survival-oriented services" that offer food, showers and clothing additionally to counselling and drug treatment.

The aim of these consumption rooms is to contribute to a reduction in drug use in public places and the provision of addiction treatment and other health and social services (EMCDDA, Drug consumption rooms, 2016), **not to enable a "comfortable" cannabis consumption**; an allegation contributed by very conservative politicians.

Yet, focussing on the legal aspects of drug consumption rooms, it is a **contradictory construction**: Dispensing, purchasing and possessing narcotic drugs/intoxicants is illegal and subject to criminal prosecution - whereas the operation of drug consumption rooms and the consumption of illegal substances within the premises is not. This situation creates legal uncertainty and impedes the social work and endangers stuff and visitors of these rooms (Akzept on Drug Consumption Rooms, 2016).

Possession and consumption of cannabis in the context of quantity and public interest in law enforcement

The possession of an illicit drug is a criminal offence in Germany and this also applies for cannabis. There is no general impunity regardless of the amount. Yet, it can be decided to waive or to desist from persecution when narcotic drugs were meant for own consumption and there is no public interest in law enforcement.

The main principle governing addicted users who have committed a crime is the so-called "treatment not punishment": this allows the courts to refrain from enforcing any final sentence under the condition that the narcotics dependent criminal undergoes treatment (§35 BtMG). It is also possible to defer the enforcement of imprisonment by up to 2 years to provide addicts with a chance to undergo therapy (§. 56 StGB) (chapter 2.3.1)

BtMG provides in Chapter VII for **drug-addicted offenders** the following options:

- The § 31a of the BtMG (Refraining from prosecution) offers the public prosecutor to refrain from prosecution if the offender's guilt could be regarded **as minor, if there is no public interest in a criminal prosecution** and if the offender cultivates, produces, imports, exports, carries in transit, acquires, otherwise procures or possesses narcotic drugs in small quantities exclusively for his **personal use**.
- Prosecution should be refrained from if the offender possesses narcotic drugs **in a drug consumption room in small quantities** exclusively for his **personal use**, which may be tolerated pursuant to § 10a, without being in possession of a written license for acquisition.

Deferment of the execution of a sentence referring to § 35 BtMG

There are various possibilities within the German Narcotic Drugs Act to refrain from prosecution and in practice this is mainly applied in connection with cannabis cases (Point, 2016) such as for the possession of small amounts of drugs for personal use

Refraining from prosecution according to § 37: If a defendant suspected of having committed a criminal offence due to an addiction to narcotic drugs and if punishment is not exceeding two years of imprisonment, the public prosecutor's office may refrain from preferring charges, with the consent of the court, if the defendant supplies proof that he is undergoing treatment to cure his addiction and his social rehabilitation can be expected

Juveniles and adolescents § 38: §§ 35 and 36 also apply to a sentence of youth custody. In this case the consent of the person in charge of the juvenile's upbringing and of the legal representative is required. Furthermore the promise of the juvenile is required that he/she attends an addiction rehabilitation treatment.

CAVE: There is no legal right of possession of small quantities of drugs nor that the possession will not be prosecuted and - if no criminal prosecution is pursued, does not automatically mean that the crime has no consequences.

- ! Public prosecutors have the option to halt proceedings in connection with **obligations** like **community service, fines** or counselling in a social institution.
- ! If the self-consumption is connected to a **third-party risk** it is not an act of self -harm any more. Personal consumption can imply public interest if this behavior could lead to imitation e.g. in **schools** or youth homes - especially if the offender is a teacher, trainer, educators etc.
- ! According to BtMG **the passing on** of only one consumer unit **by an adult** (adult in the criminal sense, so minimum 21 years old, cf. § 1 JGG) **to a minor** is a crime according to § 29a.

3.3 Driving under the influence of cannabis

Driving under the influence of intoxicants/drugs can be considered as a regulatory or criminal offence (chapter 2.3.2). This applies also to cannabis.

For **alcohol** there are threshold values provided. According to § 24a StVG (German Road Traffic Act) zero for unexperienced drivers (beginners) with less than 2 years' experience or under the age of 21. Zero applies also to professional drivers, bus drivers and truck drivers. 0.3‰ in conjunction with any other traffic offense or accident; 0.5‰ otherwise. Quantities refer to 0.5 per mille (‰) blood alcohol or 0.25 mg/l alcohol in breath. Absolute impairment of the fitness to drive exists if the driver has 1.1 ‰ or more and that is under German law a criminal offense.

Unlike alcohol, the situation for **cannabis** or other drugs is not that clear and the Länder governments implement the regulations inconsistently. Threshold values play a role but also if a person takes authorized medicinal products like Sativex or Dronabinol (chapter 3.6.2) under the supervision of a physician or inhales the smoke of natural cannabis. According to the driver's license regulation regular consumption of cannabis excludes active participation in road traffic and authorities can withdraw the driving license. According to a decision of the German Federal Constitutional Court in 2002 (BVerfG, Beschluss der 1. Kammer des Ersten Senats vom 08. Juli, 2002), the authorities are allowed to withdraw the driving license only if there are reasons to believe that the person is not able to or willing to separate cannabis consumption from active participation in road traffic, leaving thus a certain room for "responsible" consumption and refraining from driving a car after it.

Threshold level for THC: THC concentration in the blood and the ability to drive has been the subject for many discussions, court trials and even studies (Point, 2016). 2004, in a German Supreme Court decision was stated that a THC content of below 1.0 ng/ml in the blood does not constitute an acute impairment of the fitness to drive (Verfassungsbeschwerde Ordnungswidrigkeitenverord. nach § 24 a Abs. 2 StVG, 2004), BvR 2652/03). The Federal Administrative Court (Bundesverwaltungsgerichts, BVerw G 3 C 3.13 (Cannabis im Strassenverkehr, Messung des THC-Werts, 2014) confirms in their decision from 23 October 2014 this threshold of 1.0 ng/ml THC content and refers to the Threshold value committee acc. to §24a (2) StVG which defined this threshold 2002 (Grenzwertkommission 20.11.2002 (Beschluss zu §24a (2) StVG vom 20.11.2002 der Grenzwertkommission, 2002)). The definition "fit for driving" under cannabis medication is complicated: one problem is that cannabis can be traced for 24 hours and longer in the blood, depending on the frequency of use. Another problem is that during the calibration phase and dose finding of treatment with cannabis and cannabis based

medicines, the patients are not able to drive a car (Arbeitsgemeinschaft Cannabis als Medizin e.V., 2016).

There are according to the recent publication of the Working Group "cannabis for medicinal purposes" (Arbeitsgemeinschaft Cannabis als Medizin e.V., 2016) ongoing negotiations between Federal Opium Office and the Federal Ministry of Transport if medical use of cannabis can be subject of an exemption comparable to that of dronabinol or Sativex.

3.4 Cannabis Thresholds

Definition of thresholds according to BtMG

The definition of quantities according to the Section "Criminal offences" in the BtMG are very important regarding the seriousness of the offense and level of penalties.

§ 31a Refraining from prosecution and § 29 Criminal offences of the BtMG provides the following information: *" (5) The court may refrain from imposing punishment pursuant to subsections 1, 2 and 4 if the offender cultivates, produces, imports, exports, carries in transit, acquires, otherwise procures or possesses narcotic drugs merely in small quantities for his personal use"*. Since 1992 the public prosecutor can, based on § 31a BtMG, refrain from prosecution even without consent of the court if the guilt was considered as minor.

According to § 29a BtMG imprisonment of not less than one year can be imposed for illicit trades, production or supplies in narcotic drugs in quantities which are **not small**, (exempt if obtained on the basis of a license pursuant to § 3 BtMG. Depending on seriousness of the offence, imprisonment can range from three months to five years.

§ 30 BtMG defines legal procedures and penalties for "narcotic drugs in quantities which **are not small**" and then culminating in § 30a:"the sentence shall be imprisonment ranging from six months to ten years" for offences linked to "not-small quantities".

Small quantities: A small amount refers to the (gross, brutto) of an illicit drug that does not inevitably leads to criminal prosecution according to § 29, 5 and § 31a BtMG. The small amount is defined as a maximum of three consumption units and this applies to all federal Länder. One consumer unit is the equivalent quantity of a narcotic drug leading to a state of intoxication.

Normal quantities: Normal quantities - exceeding the small quantities - is punishable according to article 29, 1 BtMG. This quantity is above the small quantity acc. to § 31a BtMG), but still below the "not small quantity" (in the sense of § 29a BtMG).

Not small quantity

According to the decision of the Federal Supreme Court (BGH 3. Strafsenat, 3 StR 183/84 (Urteil "Nicht geringe Menge" von Cannabisprodukten, 1984) from 18th July 1984) is a "not a small quantity" of cannabis, when the cannabis product contains at least 7.5 g of tetrahydrocannabinol (THC) irrespective of pharmaceutical form. In most federal Länder the "not small amount" (§ 29a abs. BtMG) begins at 7.5 g pure active substance THC, corresponding to 75 g cannabis with a content of 10% of active ingredient.

According to § 29a BtMG dealing with a not small quantity of cannabis could be punished by imprisonment not shorter than one year. Under aggravating circumstances like illicit import or if organized crime is involved, the penalty can sum up to not less than 5 years imprisonment (§ 30a BtMG).

Definition of "not small quantities" of synthetic cannabinoids acc. to BGH decision 1 StR 302/13 14th January 2015 in Landshut:

The definition of the "not small quantity" of synthetic cannabinoids refers to specific mode of action and concentration. Basis is the extremely dangerous, even lethal dose of the active substance. If these data are not known the limit is calculated on the basis of the multiple of the average consumption unit of consumers not accustomed to the consumption of this drug. The potential to harm consumers is extrapolated from known substances to their homologs. As an example: the "not small quantity" of synthetic cannabinoids (JWH-018 and CP 47,497-C8) homologs was defined to begin at two grams and for JWH-073 and CP 47,497 at six grams.

3.5 Federal Länder and harmonization of thresholds

Germany is a Federal State where the Federal Länder have a certain autonomy regarding narcotic drugs policy. According to Article 83 of the German Basic Law, Federal statutes have to be executed, unless otherwise provided for by the Basic Law. The Federal Länder are responsible for monitoring the narcotic drugs trade in surgeries, pharmacies and hospitals and have jurisdiction in criminal proceedings over narcotic drugs (except last instance by the supreme Federal Courts).

There is no nation-wide definition for the application of § 31a BtMG, almost every federal Land in Germany has its own regulation or statement to the public prosecutor's Office.

Harmonization of thresholds in Germany

9th March 1994 the Federal Constitutional Court stated in the „Cannabis-Decision" (BVerfGE 90, 145 ff.) that, in case of minor offences involving the personal use of cannabis, the prosecution authorities of the Federal Länder should consider the "ban on excessive punishment" enshrined in the German Basic Law. Federal Länder were requested to ensure a "basically uniform practice of application" and, as a rule, to refrain from prosecution if the conditions set out in § 31a of the Narcotics Act apply. With its decisions of 29th June 2004 (file no: Az: BVerfG, 2 BvL 8/02) and 30th June 2005 (Az: BVerfG, 2 BvR 1772/02), the Federal Constitutional Court reaffirmed its earlier decisions on criminal liability (EMCDDA, EMCDDA Country legal profiles Germany, 2016).

Based on the decision of the Federal Constitutional Court of 1994, the Federal Government suggested, that the Land Ministries of Justice establish a uniform criteria for the practice of prosecution. Crucial point was **the determination of a "minor/insignificant quantity"** of cannabis for personal use.

Threshold values for "small amounts" of cannabis and other substances

The judicial administrations of the Länder established, different criteria and quantities for the application of § 31a BtMG in individual guidelines Almost all Länder have introduced comparable threshold values for "small amounts" (upper/lower limit) of cannabis, but not identical due to differences in the regulations of the Länder. This legal uncertainty has been evaluated in publications from the MPI for Criminal Law (Schäfer, C., Paoli, L., Grundies, V. 2006).

The German hemp association (Hanfverband) published a summary with defined amounts, thresholds and legal practices in February 2016 (Hanfverband, 2016) revealing considerable differences.

Berlin, Bremen and Niedersachsen define a small quantity as: 15 grams THC, Baden-Württembergand Sachsen 3 grams, Mecklenburg-Vorpommern: 3 – 5 gram, Bayern 4 grams, Brandenburg,

Hamburg, Saarland, Sachsen-Anhalt , Niedersachsen between 4 and up to 6 grams. The comparison of thresholds values for cannabis of the different Länder reveals a clear picture. The values are far from harmonized.

Comparison of EU thresholds and prosecution of drug offences in Europe reveal high diversity

The EMCDDA has published a comparative analysis on the different thresholds in connection with law enforcement in Europe. It was considered if countries' laws mention quantities, how they were implemented and what measurement (doses, grams, value...) were given. (EMCDDA EU: legislative approaches, 2005)"; (EMCDDA Threshold quantities for drug offences, 2016).

The collected data display considerable differences. Thresholds of narcotic drugs are treated quite differently within each country. Quantities may be given at different legal levels; in laws, in ministerial decrees, in prosecutor guidelines or sentencing guidelines. Some countries provide lists of substances, others define quantity limit only to a few substances. And - far from harmonization - different countries opt for different quantities for similar offences; e.g. Lithuania initiates criminal prosecution for possession of cannabis resin with 0.25g, many German Länder with 6g (EMCDDA Threshold quantities for drug offences, 2016).

EU harmonization efforts: EU Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking attempts to provide a framework regarding definitions and penalties. Yet thresholds or guidance in this respect are not provided.

In summary it can be stated that there is no harmonization of thresholds of illicit narcotic drugs on national nor international level. This is part of the legal uncertainty that address movements that are in favor of drug decriminalization.

3.6 Current legal status in Germany: Cannabis based therapy

The control of BtM trade – except for of BtM handling by physians, dentists and veterinarians and in pharmacies, veterinary house pharmacies, hospitals and veterinary clinics – is under the responsibility of the **Federal Opium Agency or Office** (Bundesopiumstelle), at the BfArM (Federal Opium Agency, 2016).

If in this chapter cannabis based therapy is addressed, two distinctions have to be made. cannabis (plant parts, resin, extract) can be the basis for the active ingredient in an authorized medicinal product. Medicinal cannabis based products with a marketing authorization (refer also to chapter 3.6.2) can be prescribed on narcotic drugs prescript. The prescription of narcotics, substances listed in Annex III, chapter 2.1) requires a special prescription form (Betäubungsmittelrezept, BtM-Rezept), please refer to following chapter.

Medicinal cannabis flowers or cannabis extract for self-treatment under medical supervision in accordance with § 3 abs. 2 BtMG requires special government permissions. This is addressed in chapter 3.6.4.

3.6.1 Ordinances and prescription of narcotic drugs

The Narcotic Drugs Prescription Ordinance (BtMVV Betäubungsmittel-Verschreibungsverordnung) regulates the **prescription of narcotic drugs** by physicians, dentists and veterinarians (including the maximum quantity (Höchstverschreibungsmengen) that can be prescribed.

The prescription of narcotics, substances listed in Annex III, chapter 2.1) is subject to the special regulations and requires a special prescription form (Betäubungsmittelrezept, BtM-Rezept). With the amendment from March 2013, new security features against counterfeiting and manipulation had been introduced (BfArM, 2016). It contains three copies. One for the physician, two for the pharmacy, as receipt and one for the reimbursement procedure. The front page is yellow and should include the following mandatory information:

- Patient: name and address
- date of issue
- name of medicinal product, dosage form, type and quantity of narcotic drug
- information regarding dosage or a note that the patient received a written dosage information
- Physician: Name and professional designation and address and telephone number and signature

Information panel 2 German special prescription form (Betäubungsmittelrezept)

German special prescription form (Betäubungsmittelrezept), published (BAnz AT 15.02.2013)

Apart from BtMVV the Federal Government issued statutory ordinances regulating the following sectors on the basis of the Narcotics Act:

- Ordinance on the Domestic Trade in Germany (BtM Binnenhandelsverordnung)
- Ordinance concerning the Foreign Trade in Narcotics (BtM Außenhandelsverordnung)
- Ordinance on Charges (BtM Kostenverordnung) the costs and fees chargeable for the various official acts performed by the Federal Institute for Drugs and Medical Devices (BfArM) for the purpose of monitoring the licit trade in narcotics
- Precursor Monitoring Act (Grundstoffüberwachungsgesetz GÜG) The new revised version of 19th March 2008 Precursors Monitoring Act entered into force on 19th March 2009. This Act aims to prevent and prosecute the abusive use of precursors for the illicit manufacture of narcotics. The Act regulates control and monitoring of the trade in precursors as well as criminal

and administrative offences and implement. The Ordinance on Charges serves to cover the costs that arise for the BfArM through official acts in the field of precursor control.

3.6.2 Medicinal products

Dronabinol (trans-Δ9-THC) Currently there is no authorized medicinal product based on the active ingredient dronabinol on the German market but it can be imported from the US as Marinol® or can be used as the active substance in individually prepared drugs on prescription in pharmacies. Marinol® received the marketing authorization 1985 in the United States. HIV infections were of great concern at that time. No therapy was available and patients died among other reasons due to severe loss of weight. Marinol was prescribed to stimulate the appetite (Cremer-Schaeffer, 2016). Additionally Marinol was approved for treatment of chemotherapy-induced nausea and vomiting.

Nabilone is a synthetic cannabinoid with therapeutic use as an antiemetic and as an adjunct analgesic for neuropathic pain. A nabilone based medicinal product has been authorized in Germany 2015 but is currently not marketed (acc. to BfArM internet presentation, status June 2016). Nabilone is marketed as Cesamet in the United States and as Canemes in Austria (see summary of product characteristics SmPC AOP Orphan Pharmaceuticals AG Wien). An import of Nabilone can be granted in individual cases (Cremer-Schaeffer, 2016).

Sativex®, is an oral mucosal spray with two components, Cannabidiol (CBD) and Delta-9 Tetrahydrocannabinol (THC) authorized in Germany since 2011. Sativex contains two extracts from *Cannabis sativa L.*, folium cum flore (cannabis leaf and flower. Excipients: anhydrous ethanol, propylene glycol, peppermint oil. (according to SmPC of GW Pharma Ltd (GW Pharma Ltd., 2015))

Sativex is a "complete extract" containing all ingredients of the cannabis plant. Before Sativex could be authorized the annexes of the BtMG had to be adjusted. In 2011 cannabis was added to annex II and III of the BtMG (25. BtMÄndV, see chapter 3), which for the first time permitted cannabis based proprietary medicinal products to be manufactured and prescribed (Cremer-Schaeffer, 2016).

Indication: Sativex is indicated as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.

The list of medicinal products is presented without claiming to be exhaustive and the formulations (Rezepturen) of the German prescription formulatory are addressed in the following chapter.

3.6.3 Cannabis in pharmacopoeias

The representation of cannabis and/or its withdrawal from the pharmacopoeias is an indication of the current drug policies and can be seen as an estimation of cannabis as an active pharmaceutical ingredient.

Cannabis monographs appeared in the British Pharmacopoeia as early as 1888 but were removed in 1932 (The House of Lords, Science and Technology Committee, 1998). In 1850, the United States Pharmacopeia (USP) recognized cannabis as a drug in and published an Extractum Cannabis (or extract of hemp) monograph in the United States Pharmacopoeia (Pharmacopoeia of the United States, 1851). The National Formulary and United States Dispensatory also included monographs on cannabis and

cited recommendations for its use for numerous illnesses. In response to a concerted effort by the Federal Bureau of Narcotics in the 1930s cannabis and related substances were omitted in 1942 (USP XII) and further classified as Schedule I drugs in 1970 (Gabriel I. Giancaspro, 2016).

With the growing acceptance of cannabis for medicinal purposes the different Pharmacopoeias initiated the development of **quality standards** and definitions of safe preparations in compendial standards. If medical use of cannabis is recognized in the future, guidelines appropriately adapted in monograph format are necessary to ensure identity, purity, quality, and strength of the substances.

- - The American Herbal Pharmacopeia has recently proposed a monograph for the flowers (American Herbal Pharmacopoeia, 2013).
- - U.S. Pharmacopeia Convention (USP) has published Stimuli article "The Advisability and Feasibility of Developing USP Standards for Medical cannabis" that analyzes the need for public quality standards for medical cannabis following legalization of the medical use of cannabis in several U.S. states (Gabriel I. Giancaspro, 2016)

Cannabis in German pharmacopoeias

The German Pharmacopoeia (Deutsches Arzneimittelbuch, DAB) is a collection of recognized pharmaceutical rules regarding the quality, testing, storage, dispensing and designation of medicinal products and the substances used in their manufacture. The legal basis is § 55 AMG (German Drug Law) and it is published by the BfArM in agreement with the Paul Ehrlich Institute and the Federal Agency for Consumer Protection and Food Safety.

The rules contained in the Pharmacopoeia are laid down by the German Pharmacopoeia Commission or by the European Pharmacopoeia Commission. Publication in: European Pharmacopoeia, German Pharmacopoeia (DAB) and German Homeopathic Pharmacopoeia (HAB) are binding, yet the rules can be refused or annulled for legal or technical reasons (Verbraucherschutz, 2016).

The German pharmaceutical Codex (DAC) is not part of the Pharmacopoeia and is no official register. It provides production regulations and standard procedures for batch preparations of formulations as well as individual formulations. The DAC/NRF Commission is responsible for German pharmaceutical Codex and the New Prescription Formulatory (NRF). The Federal Union of German Associations of Pharmacists ABDA appoints the DAC/NRF commission consisting of independent experts and functions as publisher for the DAC/NRF. DAC monographs contain information that summarize the pharmaceutical knowledge to each described active substance. In DAC monographs, test methods including identity, purity and content as well as storage and application requirements are described.

Cannabis is not listed in the German pharmacopoeia and cannabis (and preparations, related substances) are not listed in the European Pharmacopoeia (version checked: European Pharmacopoeia Online 9.0). But cannabis is listed in the German prescription formulatory.

The German DAC updated its Dronabinol, Cannabidiol prescription formulatory recently (published in the Pharmazeutische-zeitung) and the DAC monograph "cannabis flowers" was released in June 2016.

In summary the German pharmaceutical Codex DAC/NRF published the following information for cannabis (DAC/NRF-Werk, 2016):

- Monographs
    - Dronabinol (= Delta 9-THC) since 2001 in DAC/NRF
    - Cannabidiol (= CBD)
- Formulation instructions - Rezepturvorschriften
    - Dronabinol-capsules 2,5 mg / 5 mg / 10 mg (NRF 22.7.)
    - oleaginous Dronabinol-oral drops 25 mg/ml (NRF 22.8.)
    - oleaginous Cannabidiol-oral solution 50 mg/ml (NRF 22.10.)

Symposium of the Federal Chamber of Pharmacists: "cannabis for medicinal purposes - facts and challenges" in Berlin June 2016. During this symposium the new legal developments regarding cannabis were discussed, especially the bill 2016/0014/D amending the narcotics regulations and other provisions with the aim to legalize cannabis for medicinal purposes. The new monograph "Cannabis flowers" was introduced and quality criteria discussed that will have to be applied for cannabis for medicinal purpose (Andreas Kiefer, 2016) and details in chapter 5.4.2).

In the 54th protocol of the German committee for pharmaceutical biology, part of the German Pharmacopoeia Commission, the progress of development of monographs and procedure descriptions regarding *Cannabis sativa* were evaluated (Fachausschüsse d. dt. Arzneibuch-Kommission, 2016).

The current projects that were addressed included new monographs of the DAC (see above), thin-layer chromatographic methods for identification of different cannabis varieties, HPLC methods for identification of Cannabinoids and atom absorption spectroscopy based lead detection in cannabis flowers. The report scheduled result discussion and evaluation of incorporation of a new cannabis monograph in the German Pharmacopoeia to autumn 2016 (Fachausschüsse d. dt. Arzneibuch-Kommission, 2016).

The recent activities of the DAC/NRF and the German Pharmacopoeia Commission demonstrate that pharmaceutical environment is preparing the set for medicinal cannabis. An important step towards the implementation of the bill presented by Federal Health Ministry, Herrmann Gröhe that aims to make pharmaceutical-grade cannabis based drugs available (chapter 5.2 Cannabis for medicinal purposes: 2016/0014/D Bill amending the narcotics regulations)

3.6.4 Natural cannabis for medicinal purposes: exempt according to § 3 abs. 2 BtMG

The cultivation and/or use of cannabis (dried plant parts, resin) for self-medication is in general prohibited. Yet an exemption on the purchase of cannabis within the scope of a medically supervised and assisted self-therapy according to § 3 abs. 2 BtMG can be granted by the Federal Opium Office of the BfArM. "The BfArM may issue a license for the narcotic drugs listed in Annex I only by way of exception for scientific or other purposes in the public interest".

Applications on granting an exemption pursuant to § 3 abs. 2 BtMG can be submitted to the BfArM for the purchase of cannabis flowers and cannabis extract for medically supervised and assisted self therapy. Guidance documents and application forms are published on the BfArM and Federal Opium agency internet presentation (Bundesopiumstelle, Bundesopiumstelle: Hinweise für Patientinnen und Patienten, 2016).

Currently detailed instructions are available in the internet e.g. from the Society of Cannabis for Medicine (Grotenhermen, Franjo, 2016) explaining how to apply for such a permission. It had been a long path of development and a lot of patients faced law enforcement and sanctions before the theoretical legal options became a real option, safe for doctors and patients to receive a permission to obtain cannabis- based therapy.

In the past applications from patients were turned down by the BfArM because the treatment of a single patient were not seen as a scientific or other purpose of public interest for a license according to § 3 abs. 2 BtMG. Additionally medical treatment with cannabis was seen as problematic due to safety and quality concerns. Especially self-cultivated cannabis was considered as dangerous and not suitable for medicinal purposes.

May 2005 the Federal Administrative Court decided upon a claim of a plaintiff, a 56 year old lawyer suffering from severe multiple sclerosis, who had in vain tried to receive an exemption for cannabis treatment (BverwG 3 C 17.04; (Antrag auf Erteilung einer Erlaubnis zum Erwerb von Cannabis zur Behandlung einer Multiple-Sklerose-Erkrankung , 2005). The court stated that a general refusal cannot be justified on the assumption that the treatment of a single patient cannot be of public interest and of no scientific purpose - individual medical treatment is of public interest even though if in this case an individual medical need has to be considered and not a health benefit in general. The court acknowledged the increasing public interest in cannabis based therapy for chronically and severely ill patients and referred to the right of life and physical integrity (§ 2 abs. 2 Satz 1 GG-Basic Law) of the German Basic Law. The protection of this right is touched if a government takes measures which prevent the cure or alleviation of a disease and a physical harm is thus continued and maintained" (Fahnenstich, 2010).

Implementation of the exempt pursuant to article 3, paragraph 2 BtMG: facts and figures

Status September 2016, 900 patients possess an exempt for cannabis flowers and extract from the BfArM acc. to § 3 abs. 2 BtMG., 863 for cannabis flowers and 52 for cannabis extract, 15 permissions for both (BfArM, Bundesopiumstelle, 2016). Since beginning of 2011 up to June 2016, 1190 patients applied for an exempt (Harald Terpe, 2016).

- 2011: 60 proposals, 38 granted, 11 proposals refused
- 2015: 434 proposals, 315 granted, 12 refused
- 14. June 2016: 192 proposals, 85 granted so far, applications are ongoing

Exempt for cannabis flowers and extract acct to § 3 abs. 2 BtMG has been granted for the following indications:

- Pain (including painful spasms in multiple sclerosis - ca. 62 %
- ADHS approx. 12 %
- Depression 6 %
- Loss of appetite, cachexia 4,5 %
- Tourette-Syndrome 4 %
- Bowel disease 4%
- Epilepsy 3,5 %
- Psychiatric disorders 3 %
- Neurology 0,5 %
- Lung disease 0,5 %,
- Proposals for other indications were refused

Statutory health insurance physicians prescribed Sativex (chapter 3.6.2) approx. 22 000 times in the year 2015. Retail price (licensed pharmacies) for one gram of dried cannabis flowers is currently between 15 and 20 EUR. Calculated to the monthly need of a patient this sums up to 540 to 1800 EUR per month, depending on therapy (Harald Terpe, 2016).

The number of proposals are rising, demonstrating that there is a demand for this kind of therapy. The price calculation shows that the self-therapy is a financial burden to the patient especially when considering that only severely or chronically ill patients have a chance to get an exempt.

3.7 Current legal status in Germany: self-cultivation

Legalization of self-cultivation of cannabis for therapeutic purposes - announced BVerwG, Judgment/Decision 06th April 2016: **… self-cultivation of cannabis for therapeutic purposes is exceptionally permissible**

Federal Administrative Court in Leipzig dismissed the appeal of the German Health Authority and obligated the BfArM to grant the applicant (a seriously ill Multiple sclerosis patient) an exceptional permission to grow cannabis for his own purposes. This sentence has the consequence that **self-cultivation of cannabis for therapeutic purposes is exceptionally permissible**

BVerwG 3 C 10.14 of the Federal Administrative Court Leipzig concerning: self-cultivation of cannabis for therapeutic purposes is exceptionally permissible (Bundesverwaltungsgericht, BVerwG, Judgment/Decision 2016-04-06 Press release Nr. 26/2016 , 2016)

According to § 3 abs. 2 BtMG cultivation of cannabis can only be allowed upon exemption for scientific purposes or for reasons that lie in the public interest. In this case the treatment of the severe ill applicant with home-grown cannabis was defined as in the public interest.

It was considered as proven that the applicant had no access to other cannabis as narcotic drug and no affordable and available alternative medical treatment – since the medicinal hemp available in pharmacies is too expensive for the applicant. His applications for coverage at his health assurance reimbursement of his health insurance had been repeatedly turned down. Due to his occupational disability he is not able to finance the cannabis on his own. An action for assumption of costs to the Social court cannot reasonably be expected in this case. The court also did not see grounds for refusal in §5 BtMG – control and safety of drug trafficking was not seen as endangered. The applicant was deemed experienced with the application of cannabis for medical purposes, years of self-therapy trained him to apply and dose appropriately. The court saw no indication potential abuse. Additionally the court did not see a violation of agreements of the Single Convention on Narcotic Drugs from 1961. Under the explained conditions and based on the demands of the German constitutional law (§ 2 abs. 2, 1 GG) "respect for the integrity of a human being", the exceptional permission had to be granted.

This sentence reduced the discretionary powers of the BfArM to nil with the consequence that the BfArM is not only obliged but also empowered to allow the applicant the self-cultivation of cannabis. **September 30th 2016, the first permission** for self-cultivation was granted (BfArM: Ausnahmeerlaubnis Eigenanbau, 2016), details are presented in the next chapter.

4 Recent developments in Germany towards legalization of cannabis

Legalization strategies including legalization for recreational and medical purposes: these topics are, as discussed before, not identical yet interrelated. Despite considerable controversy between the attitudes towards recreational versus medicinal use of cannabis and whether health, social or crime aspects were addressed the political environment developed towards an acceptance of a more liberal drug policy. The bill of the Federal Ministry of Health amending the narcotics regulations and other provisions from 08th January 2016 legalizing cannabis for medicinal purposes and the bill of the Cannabis Control Act legalizing cannabis for recreational purposes can be considered as a result of this change of attitude. In the following legal and administrative initiatives preparing the ground for both bills are introduced.

Chronology of activities setting pace for the legal change

Background and retrospective of the German political efforts towards legalization of cannabis – the interest and pressure rose from different sides:

November 2013 - initiative of 122 criminal law professors

122 criminal law professors and experts expressed the necessity to review the German narcotics drug act. They submitted a petition to the German parliament including the request to implement a committee of enquiry by the German parliament (Schildower Kreis Res., 2016).

Translated commitment of the signees acc. to their internet presentation: The signees wish to rise awareness of the legislators on the unintended harmful side effects and consequences of the criminalization of certain drugs. They want to encourage the parliament to take account of its constitutional mandate in general and the scientifically based principles of criminal law and criminal policy in particular through the establishment of an inquiry commission (enquête publique).

Schildow Circle (Schildower Kreis) - Circle of German legal experts that fight for legalization of cannabis

Lorenz Böllinger, emeritus professor of criminal law at Bremen University, founded the ‘Schildow Circle'. It now consists of 123 criminal law professors (state 2015) who are campaigning to legalize the sale and ownership of cannabis. The Schildow circle expressed their doubts regarding German drug policy based on prohibition and call for a revision of the Narcotics Drug Act. Motivation and reason of the experts of the Schildow Circle according to their internet presentation:

- global failure of criminal control of drug demand and supply
- enormous profits on the black market
- growing shadow economy fueled by globalized black markets generating a circuit of crime
- destabilizing impact on global financial markets and national economies
- scientific evidence that appropriate health actions and regulation, criminal sanctions, as well as welfare and educational measures show better results than a restrictive drug policy and criminalization
- they see their arguments supported by experience from nations that have a more liberal drug policy for example Netherlands, Switzerland, Spain, Portugal
- U.S.A. paradigm shift from "war on drugs" to public health strategies (since the Obama Government). On December 10th 2009, the House of Representatives established a committee to investigate the failure of drug policy in the United States.

Schildow circle statements in summary:

Schildow circle considers drug prohibition as a failure. It is stated that the repressive drug policy creates the problems rather than the narcotic drugs: the criminalization of the majority of drug users is a major problem and injustice. Most consumers live a normal life. Even dependent consumers are often socially integrated. People with problematic drug use need help not prosecution. Consumers are discriminated, prosecuted and driven into criminal careers. Therefore prohibition is seen as harmful to the society. It encourages organized crime and the black market. The results are violated civil rights and a corrupted constitutional state.

The war between drug cartels and police forces creates a spiral of violence leading to a quasi-militarization of the police and thus eroding state structures. The profits from the drug black market are huge, creating parallel societies and money flows. In certain countries the massive power of globally acting criminal cartels increase the risk of failure of civil society.

Costs of prohibition: The citizens are victims of drug-related crime. Every year billions are spent for law enforcement, which could better be spent for prevention and health care. The State forgoes tax revenues that would be paid if e.g. cannabis is marketed legally. This is an aspect the cannabis Control act is addressing to (chapter 6.2).

Consumer and youth protection is impeded. Consumers are exposed to dangerous diseases (such as AIDS, hepatitis C) due to uncontrolled and risky forms of consumption. Normal youthful experimentation behavior is criminalized with the result that young people face the risk to be permanently stigmatized (Schildower Kreis, 2016).

Spring 2015 - government releases statements in favor of medical cannabis

February 2015 - the German Federal Drug Commissioner, Marlene Mortler, confirmed her support for the medical use of cannabis but stated at the same time that she sees great dangers in the use of cannabis as stimulant (Genussmittel) in an interview with the newspaper “Die Welt” February 2015. Marlene Mortler strongly rejects the legalization of cannabis for recreational use, pointing to health risks. "We must not underestimate the health risks for young people, in particular… "Regular cannabis consumption leads to considerable health damage, and can lead to psychoses and addiction."

March 2015 - In the federal government's reply to the parliamentary question (Kleine Anfrage) put by parliamentarians and members of the “Die Linken” on “facilitation of medical treatment with cannabis” (Dt Bundestag- Kl. Anfrage, 2016) the Federal Drug Commissioner Marlene Mortler and the Federal Minister of health Herrmann Gröhe confirmed the plan to draft a law with the aim to lower the barriers to the use of cannabis for medicinal purposes.

Hearing of the Committee on Petitions of the German Federal Parliament on “cannabis for medicinal purposes” 23rd March 2015. Franjo Grotenhermen, chairman of the Working Group “cannabis for medicinal purposes” launched the petition 2014, supported by DHV (German Hemp Association), the Greens and Die Linke. During this consultation the Federal Minister of health, Herrmann Gröhe, confirmed again the plan to draft a law in favor of medicinal use of cannabis.

Recent regional (Länder) initiatives: cannabis for recreational purposes

June 2015: proposals for cannabis sales points in Berlin

Monika Herrmann, Greens party mayor for the Berlin inner district, Friedrichshain-Kreuzberg, filed a proposal for four sales points for cannabis. Only registered adult residents were planned to be entitled to buy up to 60 grams of cannabis every month (Friedrichshain-Kreuzberg, 2016).

Herrmann and supporters state the following in their proposal: Berlin addiction care filed June 2015 a joint statement: "*cannabis is today already "more or less freely available" in an unregulated illegal drug market."* She argued that even though cannabis sales are outlawed, in reality, it is easy to purchase. In this sense it's not about liberalizing the cannabis market, but an intervention in the existing drug markets. A shift away from the fight against a black market towards controlled regulated retail system under strict conditions. That is according to their opinion the only way to protect consumer and minors (Fixpunkt Berlin, 2015).

The proposal for a special permit according to § 3 BtMG was turned down by the BfArM. Herrmann filed an appeal against the decision of the BfArM 04.12.2015 (Friedrichshain Widerspruch, 2016). The appeal was rejected in February 2016 (BfArM Berlin, 2016).

September 2015: Frankfurt model project for a controlled delivery of cannabis

Proposal of the parliamentary group of the FDP to Hessian parliament 19/2420; 15. 09. 2015 (Hessischer Landtag, 2016)

The parliamentary group of the FDP called at the Hessian parliament for support. The Frankfurt Health Councilor, Rosemarie Heilig, intended to introduce a model project of controlled delivery of cannabis in Frankfurt Main. Aim of the project: gaining insights into the possible benefits and the effects of loosening the cannabis ban e.g. consequences for the development of a black market, consumer behavior and health consequences.

The project is planned in close collaboration with research centers, addiction help organizations, police, public prosecutor's office and drug experts. Measures had been planned for protection of minors and consumers.

March 2016: Scientifically monitored project with controlled cannabis dispense in Bremen

The Bundesrat Initiative started from the Senat of Bremen (Landtag Bremen, 2016) for permission of scientifically monitored projects with local controlled cannabis dispense, (Bremische Bürgerschaft, 2016). In connection with this initiative a bill was presented that included a concept of local controlled cannabis dispense.

Bill amending the narcotics regulations by adding § 10b to BtMG) for permission of scientifically monitored projects with local controlled cannabis dispense 16.03.2016 (Dt Bundestag, Kai Ambos , 2016)

The bill presented by 11 reputable legal experts and judges including Prof. Kai Ambos, University Göttingen, aims to enable government to gain experience with a controlled release of cannabis for a new regulation strategy. The concept of local controlled cannabis dispense takes up and develops further the concept of drug consumption rooms acc. to § 10a BtMG (chapter 3.2Drug consumption rooms). Taking §10a BtMG into account the bill widens this section for model projects that allow the setup of regulated and controlled cannabis delivery points to gain empirical data on drug consumption. The bill foresees a scientifically accompanied project drug retail for personal use for consumption of persons from age 16 on.

Safety measures include pass port control and registration. Cannabis delivery points have a license period of approx. 3 years and will get their cannabis from the (to be established, chapter 5.2) cannabis agency at the BfArM, thus guarantying high quality of cannabis products.

The legislative initiative stipulates that the new law is in force for 7 years, including regular evaluation and reporting periods. The cannabis delivery points are subject to legal and location restrictions similar

to that introduced in the Cannabis KT bill (chapter 6.2). The governments of the Länder will be empowered to license and control the cannabis delivery points.

30th September 2016: BfArM granted first time self-cultivation of cannabis

In spring the Federal Administrative Court in Leipzig dismissed the appeal of the BfArM and declared that self-cultivation of cannabis for therapeutic purposes is exceptionally permissible (chapter: 3.7). September 30th a seriously ill Multiple Sclerosis patient received the first exceptional permission to grow, harvest and use cannabis for a monitored self-therapy acc. to § 3 abs. 2 BtMG.

This temporary exempt for self-cultivation with cannabis will cease 30th June 2017. Until then the MS patient can cultivate up to 130 cannabis plants per year. The exempt is temporary because the legal situation is expected to change. The bill 2016/0014/D amending the narcotics regulations and other provisions drafted by the German Health Ministry is expected to come into force 2017 and will thus change the availability and reimbursement options of pharmaceutical grade cannabis (chapter 5.2). The exempt certificate (available over the Working group medicinal cannabis webpage (BfArM: Ausnahmeerlaubnis Eigenanbau, 2016) provides detailed instructions regarding safety measures, reporting and documentation of used and disposed plant parts. The exempt regulates that a maximum of 20 cannabis plants shall be cultivated in parallel in the designated cultivation area. The cultivation area is in this case, rather bizarre, the bathroom. Changes in medication regime, supervising healthcare professionals or location have to be notified to the BfArM. IN SUMMARY it must be stated that the instructions and reporting obligations are demanding and require an intense support from a medical doctor that exceeds the normal health care. The safety measures preventing misuse are comprehensible yet a severely ill patient will hardly be able to cope with these requirements.

5 Legalization of cannabis for medicinal purposes

5.1 Cannabis for medicinal purposes in Germany: facts and figures

Currently a prescription for medicinal cannabis (dried cannabis flowers and extract) can be obtained from a physician, the BfArM exemption procedure follows (chapter Ordinances and Prescription of narcotic drugs). Application to the BfArM for patient-specific exemptions to purchase medicinal cannabis from pharmacists are possible (3.6.4 Natural cannabis for medicinal purposes: exempt according to § 3 abs. 2 BtMG). According to data collected on 1 October 2015, 527 patients in Germany were granted this type of exemption. The BfArM generally charges a fee of EUR 75 for issuing the exemption in line with legal requirements. For patients who are insured under the statutory health insurance system currently have to bear the costs of medicinal hemp or extract and for drugs with dronabinol or nabilone. (source: Bill - Act amending the narcotics regulations and other provisions (Federal Ministry of Health, 2016).

The monthly treatment costs for medicinal hemp, estimated on the basis of figures for 2014, are EUR 1 800 per patient, depending on the daily requirement and an average price of about EUR 18 per gram. For dronabinol drops, the monthly treatment cost are calculated EUR 250 to 500, for dronabinol capsules, EUR 720 to 1 440 (Cannabiskontrollgesetz, 2016).

5.2 Cannabis for medicinal purposes: Bill 2016/0014/D amending the narcotics regulations and other provisions

2016/0014/D Bill amending the narcotics regulations and other provisions (8th January 2016), first reading (07th July 2016) of the draft in German parliament (Bundestag),

The purpose of the bill is to enable the marketing and prescription of pharmaceutical-grade cannabis based drugs (including medicinal hemp, i.e. pharmaceutical-grade dried cannabis flowers and cannabis extract) with the aim to give specific, particularly chronically and seriously ill patients access to pharmaceutical-grade cannabis dispensed by pharmacists. The amendment is meant to make cannabis available for appropriate indications and therapeutic purposes where no therapeutic alternatives exist.

Key objectives of the amendments to the Narcotics Act (BtMG) are:

- to grant patients access to medicinal cannabis based drugs (including for example medicinal hemp, i.e. dried cannabis flowers and cannabis extracts) of pharmaceutical grade quality - without endangering the social security and control of the narcotics trade.
- marketing and prescription: to enable the marketing and prescription of cannabis for medicinal purposes by deleting cannabis from Annex I and Annex II and to amend the listing of cannabis in Annex III. In accordance with the remaining narcotics legislation requirements, health care professionals are entitled to prescribe pharmaceutical-grade medicinal cannabis with appropriate indications.
- supply restricted to pharmacies/entitled medicinal institutions: medicinal cannabis based drugs are dispensed to patients by pharmacists
- legalization of importation and cultivation: To ensure the adequate quality-assured supply of medicinal cannabis in Germany, importation and the cultivation of cannabis for medicinal purposes shall be allowed.
- Cannabis agency as a prerequisite for the state-regulated cultivation of medicinal cannabis in Germany. The bill stipulates the establishment of a state agency in accordance with international requirements of the 1961 Single Convention on Narcotic Drugs :e.g. regulating the cultivation of cannabis for medical purposes.
- obligation for patients receiving a cannabis based treatment to take part in a research program. Aim is to monitor the patients well being and to gain more insights into all pharmacological effects of cannabis.

The bill excludes home cultivation: home cultivation of cannabis for self-therapy is not considered as safe for health and regulatory reasons.

Cannabis agency at the BfArM: The German state agency at the BfArM is planned in congruence with the definition of the 1961 Single Convention on Narcotic Drugs (articles 23 and 28). Additionally the German Cannabis Agency system refers to experience and legislation in the Netherlands, where consumption of cannabis for medicinal purposes is allowed since 2003 (see below). The German state agency has the following tasks: controlling the cultivation of cannabis, quality testing (ensuring pharmaceutical grade), buying, issuing tenders to cover demand, organization of delivery to wholesalers and pharmacists, preventing unauthorized use, ensuring constant availability as well as licensing companies involved in the production, packaging and distribution chain. The tender procedure has to follow the provisions of public procurement law. Additionally the state agency determines the price of cannabis for medicinal purposes.

Information panel 3 Dutch Office of Medicinal Cannabis

Dutch Office of Medicinal Cannabis (Bureau voor Medicinale Cannabis, OMC)

The Office of Medicinal Cannabis OMC (Dutch Cannabis bureau - Bureau voor Medicinale Cannabis, 2016) was established in March 2000. It started acting as a National Agency on 1 January 2001. The OMC is an organization of the Dutch Government, responsible for the production of cannabis for medical and scientific purposes.

The OMC has a monopoly on supplying medicinal cannabis within the Netherlands for medical use to pharmacies, licensed doctors, veterinarians and licensed research facilities. Cannabis is cultivated under specific, controlled conditions by growers who are licensed by the OMC. Preparation and handling of all import, export and national licenses and exemptions for working with cannabis products within the Netherlands is also under the responsibility of OMC.

The quality of the medicinal cannabis is guaranteed by a constant supervision of the grower and the distributors. Cannabis in pharmaceutical grade quality (dried female flowers) became available in Dutch pharmacies in September 2003, on prescription only.

Medicinal cannabis available in the Netherlands through Dutch pharmacies: There are three varieties of medicinal cannabis: Bedrocan, Bedrobinol and Bediol. Each variety has its own predetermined strength and composition (Dutch Ministry of Health, 2016).

- **Bedrocan**: THC content ca 19%, CBD content < 1%
- **Bedrobinol**: THC content ca 12%, CBD content < 1%
- **Bediol**: THC content ca 6% about, CBD content 7,5%

A selection of **indications** is published in the patient information site of the OMC including pain and muscle spasms or cramps associated with multiple sclerosis or spinal cord damage, nausea, vomiting, loss of appetite, weight loss due to cancer, chemotherapy or radiotherapy or AIDS, chronic pain and Tourette syndrome. Patients are requested to address the physician for therapeutic advice. Additionally the patient is informed that **cannabis is not a cure** for above mentioned diseases, but may have the potential of relief. Cannabis treatment has shown in some cases a positive effect as co-medication regarding reducing side effects and lowering the necessary dose of main medication.

Medicinal cannabis is **not automatically covered by healthcare insurers** in the Netherlands. Some healthcare insurers provide partial cover through supplementary insurance (source see above).

The bill proposes amendments to the following regulations:

- German Narcotics Drug Act (BtMG)
- Changes to the annexes of BtMG: deletion of the listing 'cannabis (marijuana, plants and parts of plants belonging to the cannabis species)' in Annex I (non-marketable narcotics) and Annex II (marketable, non-prescription narcotics) from the Narcotics Act (BtMG) and amendment of the listing of cannabis in Annex III (marketable and prescription narcotics)
- Narcotics regulations
- Social Security Code Book V (SGB V) to regulate the eligibility of cannabis products. For specific cases, there will be an option to have costs covered by the statutory health insurance system
- Commodities Control Act (GÜG) (Article 5) adapting the penal provisions EU law on drug precursors.

- Ordinance concerning the Foreign Trade in Narcotics (BtMAHV) (Article 2)
- Narcotics Prescription Ordinance (Article 3) (BtMVV).

Amendment to the SGB V German Social Security Code, Book V

In addition, the option for reimbursement by the statutory health insurance of cannabis based medical treatment is facilitated. This is foreseen to be defined by a new paragraph 6 to article 31 SGB V (German Social Security Code, Book V - Fünftes Buch des Sozialgesetzbuch (Arznei- und Verbandsmittel).

The following paragraph 6 is added to § 31 of SGB V *"(6) Insured persons with a severe chronic illness (§ 62(1)(8)) are entitled to treatment with cannabis in dried flower form or extract and to drug treatment with the active ingredients dronabinol or nabilone, if"*

1. there is no generally recognized therapy available that can be expected to be beneficial for the patient
2. the prospect of a positive effect on the progression of the illness cannot be completely ruled out
3. insured persons participates in an non-interventional study of an ongoing research program until 31st December 2018

The patient has to suffer from a severe and chronic disease as defined in the chronic sufferers (G-BA Chroniker-Richtlinie, 2016) directive of the Joint Federal Committee (GBA), providing the definition of serious chronic diseases and exemptions under article 62 par. 1 sentences 5 and 10. § 92 Para 1 sentence 1 SGB V.; the decision is taken by health insurances case by case.

According to the bill it is planned that the Federal Joint Committee authors a new directive based on the results of the non-interventional study program until July 31st 2019 where guidance for prescribing cannabis based therapy is provided: definition under which conditions cannabis based therapy is reimbursed by statutory health insurance.

The bill has no intention to legalize cannabis for recreational use!

Amendment of the Narcotics Act includes:

- The cultivation of cannabis for **medical** purposes and **n o t** for recreational purposes
- In Annex I (non-marketable narcotics) the following listing is deleted: cannabis (marijuana, plants and parts of plants) " **unless intended for illegal cultivation"** (dt Gesetzentwurf Änd BtM Vorschriften, 2016)

5.3 On the way to its adoption – next steps

National Regulatory Control Council (Nationaler Normenkonntrollrat)

The Bill amending the Narcotics Act contributed by the federal government of the German Republic has been submitted officially by chancellor Angela Merkel to the president of the federal council, Prime Minister Stanislaw Tillich, on 6th of May 2016 according to § 76 abs. 2 of the Constitutional law. The submission of the bill adopted by the German government includes the recommendations given by the National Regulatory Control Council (Nationaler Normenkonntrollrat) acc. to § 6 abs. 1 NKRG, are provided. The NKR confirmed that the Federal Ministry of health presented data regarding the costs transparent and comprehensive.

Notification procedure - 2015/1535 procedure

The bill amending the narcotics regulations and other provisions has been sent to Länder and associations. At the same time a EU notification process has been initiated.

The bill has to be notified because Directive 2015/1535 applies to all technical regulation concerning industrially manufactured, agricultural and fishery products including chemical compounds - and narcotics are considered here as chemical compounds. The notification procedure: according to Directive (EU) 2015/1535 Member States must inform the Commission of any draft technical regulation they plan to introduce before they are adopted in national law with the aim to prevent trade barriers. The Commission immediately informs other EU countries via TRIS technical regulations information system (EC TRIS, 2016).

After closure of the notification procedure the bill will be sent to the federal cabinet.

Standstill period of 3 months: during standstill period the Commission and other EU countries examine the proposed draft regulation and have the opportunity for comments. The drafted technical regulation cannot be adopted meanwhile. Standstill period can be extended to up to 18 months, depending on the circumstances.

Closure 2015/1535 procedure: At the end of the 2015/1535 procedure (European Commission - Single markets and standards, 2016), the Member States are obliged to inform the Commission of final version. Commission and Member States are allowed to check whether the notifying State has taken into account the reactions received from other countries.

The Directive also provides for an **urgency procedure**, which is designed to allow the immediate adoption of a national draft (without three-month standstill period), subject to certain conditions, i.e. ‘serious and unforeseeable circumstances relating to the protection of public health or safety. does not apply and the notified text can be adopted immediately.

5.4 Considerations and statements of committees

5.4.1 German Medical Association´s review regarding medical efficacy of cannabis based treatment

The German Medical Association (Arzneimittelkommission der deutschen Ärzteschaft AkdÄ) provided March 2015 an overview of the studies relating to the therapeutic use of cannabinoids (Arzneimittelkommission der deutschen Ärzteschaft, 2016). The systematic review to evaluate the therapeutic potential of cannabis and cannabinoids based on selective literature research including data base PubMed. For every indication (in discussion) comments and recommendations were provided:

- **Indication Spasticity:** in moderate to severe forms of multiple sclerosis – the only approved indication in Germany. The medicinal product is Sativex, Almiral Hermal GmbH. In the benefit assessment of pharmaceuticals in accordance with the German Social Code, Book Five (SGB V), § 35a, the Federal Joint Committee (G-BA) defined little added value in comparison with standard therapy with Baclofen or Tizanidin (Gemeinsamer Bundesausschuss, 2016). Pivotal study included 572 patients, 272 patients (47,6 %) felt a positive effect (= reduction of the spastic > 20 %). A placebo controlled second study and other clinical data **confirmed the benefit.**

- **Indication pain in MS:** Cannabinoids showed also **beneficial results** for pain in MS.
- **Indication nausea and sickness in cancer treatment:** The efficacy of cannabis based therapy for nausea and sickness resulting from treatment for cancer cytostatic therapy are well investigated and **efficacy has been confirmed**. Since more effective general accepted therapies are available cannabis is not first choice.
- **Indication loss of appetite and weight:** Beneficial efficacy has been shown for loss of appetite and weight and for HIV/AIDS-associated anorexia. Yet the evidence was not deemed sufficient.
- **Indication cancer and Alzheimer disease:** Cannabinoids were also used for cancer and Alzheimer patients and again **efficacy has not been proven**.
- **Indication Chronic pain, neuropathic pain**: **positive effect** has been proven in most studies The Akdae recommends a therapeutic attempt if other treatments failed to alleviate the pain.
- **Palliative care:** Cannabinoids stimulates the appetite, brightens the mood and can help patients to sleep, therefore the use in palliative care can be considered as beneficial.
- **Indication Shizophrenia**: It is discussed that Cannabinoids have a positive effect on schizophrenia – currently there are no clinical data that provide enough evidence for this indication.
- **Indication Tourette syndrome and Parkison disease:** Akdae considers evidence of current data and information as not strong enough.

Not all available clinical data show strong results. Sometimes cannabis has been taken for a numerous and diverse indications and studies have often included very small numbers of patients leading to a limited relevance. In summary the committees see cannabis as a medicinal product with limited medicinal value for special medical indications (palliative treatment and MS). The committees see the medical use of cannabis plants and parts of the plant linked to the risk of abuse and favor therefore the restricted use of standardized and approved medicinal products.

According to the current state of knowledge, the committees do not see an advantage in the use of medicinal cannabis ("Medizinalhanf") or other substances derived from the cannabis plant over a therapy with an approved medicinal product containing defined and controlled content of THC and/or CBD (Arzneimittelkommission der deutschen Ärzteschaft, 2016).

AKdae states that a general rejection of cannabis as an alternative therapy is not justified especially if other possibilities have been exhausted. Additionally AKdae sees no justification in the refusal of reimbursement of costs for individual attempts to help patient with a cannabis based therapy if there is no alternative, especially if there are reasons to believe that patients in palliative care can benefit from cannabis.

5.4.2 View of German pharmacists and German medical association and drug commissions

In the Statement from the German Medical Association and the drug commissions of the German Medical association and the German Pharmacists Berlin 04th February 2016 (Bundesärztekammer u Arzneimittelkommission, 2016) the extension of prescribability of cannabis based medication is in general supported. Yet, the committees expressed the following concerns:

- **lack of scientific evidence** for the medicinal use of cannabis flowers – compared to the medical use according to indication of authorized medicinal products or formulations
- Problem of **dosage** when cannabis flowers or plant parts are administered

- Joint**: smoking** of cannabis includes the health risk similar to that of smoking tobacco

And rejected the prescribability of natural cannabis (dried plant parts). The commission addressed that they do not see an advantage of natural cannabis over approved medicinal products and doubts were expressed regarding the therapeutic efficacy of natural cannabis.

Recommendation of the Health Committee and the Committee on agricultural policy and consumer protection

The Health Committee and the Committee on agricultural policy and consumer protection recommend referring to in § 76 (2) of the constitutional law to the Federal Council regarding the drafted law to take the following position (Ausschüsse Gesundheit, Agrar u. Verbraucherschutz, 2016):

The committees considers the participation in an AWB and provision of data as a condition - prior to granting the benefit of cannabis treatment - as problematic. Therefore this part of the bill is not approved by the committees. Yet the data collection and knowledge acquisition is considered as justified but in an amended form:

Data from these non-interventional observational studies shall be mandatorily sent to the BfArM. Contractual physicians shall be deemed to send the anonymized data to the BfArM after the patient has given the informed consent.

The committee expressed concerns regarding consistent quality and efficacy and requested standardization and guarantee of pharmaceutical quality of cannabis. In summary the committee recommended the Bundesrat to raise no objections against the bill.

View of pharmacists

During the symposium of the Federal Chamber of Pharmacists in Berlin, June 2016 the ABDA (Federal Union of German Associations of Pharmacists) published a position paper to cannabis, (ABDA, 2016). ABDA stressed that the benefit of a cannabis based therapy is disputed and did not take a clear positive position and recommended a critical review ´whether cannabis should be legalized for recreational purposes – emphasizing the elevated risks of accident, the association of cannabis with mental disorders, such as anxiety and depression, and possible development of addiction.

ABDA agreed with the BfArM and the governmental bill: home cultivation of cannabis for self-therapy cannot be considered as safe and cannabis should be only available upon prescription and in pharmacies. The pharmaceutical quality has to be guaranteed for cannabis based medicinal products – taking into account that the THC content varies considerably regarding cultivation techniques and botanical variety.

The Federal Chamber of pharmacists (BAK) offered to prepare a reliable and standardized formulation for application of cannabis for medical purposes in collaboration with the BfArM, e.G. for single dose cannabis flower preparation or steam inhalation with a standardized dronabinol equivalent.

Michael Hörnig, Kommission Deutscher Arzneimittel Codex / Neues Rezeptur Formularium (DAC/NRF) criticizes the dosing accuracy and pricing during Symposium of the Federal Chamber of Pharmacists in Berlin, June 2016 (ABDA, 2016): Since the content of THC or Cannabidiol (CBD) differs considerably a prescription based on gram of dried plant part cannot be accurate enough for a reliable dosage. For reimbursement and prescription practice, it should be considered to use THC-/CBD equivalents instead of gram. The bill determines a fixed manufacturers' delivery prices (Herstellerabgabepreise). It should be considered that cannabis is a raw material and not a formulated recipe medicines (Rezepturarzneimittel) or a finished medicinal product.

5.4.3 Summary - The question is what is expected from this law and how many patients would benefit from it?

If one assumes that those patients that have applied for an exempt for cannabis flowers and extract acc. to § 3 p 2 BtMG would also benefit from the drafted law, we have the following picture (for details chapter 3.6.4) : Status June 2016, 779 patients possess an exempt for cannabis flowers and extract acc. to § 3 abs. 2 BtMG and up to June 2016, 1190 patients applied for an exempt.

- ? Taking this into account, one could say that this bill has almost an "orphan designation" if figures are compared to the orphan designation according to the EMA homepage (EMA: orphan designation, 2016). Orphan drugs have a prevalence of not more than 5 in 10,000 in the EU and the medicinal product must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating.
- ? The medical benefit of cannabis is discussed controversially, scientific studies and meta data studies do not confirm an overall positive picture (chapter 5.4)
- ? There are approved medicinal products available like Sativex and Dronabinal. Statutory health insurance physicians prescribed Sativex approx. 22 000 times in the year 2015 (Harald Terpe, 2016).

A lot of effort for a disputed therapy, beneficial for few patients. Thus it is justified to raise the question: are patients with unmet medical need the only reason for this drafted law?

This bill closes legislative loopholes:

In the so-called "**Nikolaus – judgement**" the Federal Constitutional court ruled 06. December 2005, that it is incompatible with the German constitutional law and welfare state principle that an alternative therapy, with prospect of cure and/or at least positive effect, for a severely ill patient, insured under the statutory health insurance scheme, is not granted. For this patient no other treatment – treatment that is under the reimbursement scheme of the health insurance, was available. So cannabis based treatment had been considered as an alternative.

The constitutional complaint of an 18 year old patient suffering from a rare and severe disease has an impact on the obligation of the statutory health insurance to reimburse new treatment methods in cases of regular fatal or life-threatening diseases in ambulant medical care (Nikolaus Urteil (1 BvR 347/98), 2005).

Self-cultivation of cannabis for therapeutic purposes is exceptionally permissible since the Federal Administrative Court in Leipzig dismissed the appeal of the German Health Authority and obligated the BfArM to grant the applicant (a seriously ill Multiple sclerosis patient) an exceptional permission to grow cannabis for his own purposes (chapter 4). With the new law self-cultivation is not necessary anymore, since cannabis based therapy is legal and natural cannabis can be provided in pharmaceutical grade via the Cannabis Agency (BfArM). With the ban on self-grown cannabis, quality and safety concerns are met. A medicinal product has to comply with adequate quality standards and rules out self-cultivation.

6 Legalization of cannabis for recreational purposes - Cannabis Control Act (CannKG)

6.1 Development

The call for a more liberal drug policy from dedicated users of cannabis for recreational purposes is not new. Yet the pressure rose also from politicians and legal experts as well as from police officers. Background and retrospective of the German political efforts towards legalization of cannabis is provided in chapter 4. Here lies the focus on the proponents that have the decriminalization for cannabis for recreational purposes in mind because they see that prohibition did more wrong than good. Interestingly these supporters come from legal/ law enforcement side – were you normally expect opponents of a liberal drug policy.

Cannabis legalisation initiatives

Schildow Circle (Schildower Kreis): Circle of German legal experts that fight for legalization of cannabis

Lorenz Böllinger, emeritus professor of criminal law at Bremen University, founded the 'Schildow Circle'. It now consists of 122 criminal law professors who are campaigning to legalize the sale and ownership of marijuana. The Schildow circle expressed their doubts regarding German drug policy based on prohibition and call for a revision of the Narcotics Drug Act. They submitted a petition to the German parliament including the request to implement a committee of enquiry by the German parliament (Schildower Kreis, 2016) and chapter4.

LEAP Law Enforcement Against Prohibition Germany

Law Enforcement Against Prohibition (LEAP) is an international non-profit organization comprising of former and current police officers and legal experts. They are dedicated to a liberal drug policy their slogan: "Against War on Drugs" (Law enforcement against prohibition, 2016). LEAP was founded 2002 in the United States. Today LEAP has members and supporters in 190 countries including Germany. The members of LEAP Germany include among other police officers, judges, prosecutors, criminal law professors, lawyers, as well as several members of the German Bundestag (LEAP Deutschland, 2016). LEAP is in favor of a decriminalization drug policy and filed 19th April 2016 an open letter to Chancellor Angela Merkel.

On the occurrence of the UN General Assembly Special Session (UNGASS) on the world's drug problem the former police commissioner of Münster, Hubert Wimber, and the „Law Enforcement Against Prohibition" (LEAP) group asked for support of a progressive drug policy and to end the "war on drugs"

Based on their professional experience LEAP states:

- the current legislation waste valuable resources of the police in pursuing of drug consumers of cocaine. These resources are missing in other areas.
- States all over the world have lost control of criminal drug markets
- "War against drugs" has caused more problems as solved. Negative consequences of the "war on drugs" and thus associated exorbitant profits of criminal drug cartels have resulted in a drastic deterioration in the human rights situation in many production and transit countries such as in Mexico.

- Criminal markets do not know youth protection or a quality control

This attitude **contradicts the UNGASS statements** compiled and published in the drafted resolution "Our joint commitment to effectively addressing and countering the world drug problem" in April 2016 (UNGASS, 2016).

The resolution is kept very general but the focus is on law enforcement and prohibition. A chapter is dedicated to ensuring the availability of and access to controlled substances for medical and scientific purposes **a n d** preventing their diversion. No exempt for cannabis and no support for a more liberal policy based on decriminalization.

Marlene Mortler, Germany's commissioner on drug-related issues, **strongly rejects the legalization of cannabi**s, pointing to health risks. "We must not underestimate the health risks for young people, in particular," reads a statement on the commissioner's website. "Regular cannabis consumption leads to considerable health damage, and can lead to psychoses and addiction."

In this area of tension the Cannabis Control Act aims to legalizes cannabis for recreational purposes under certain circumstances. This a bill of the Fraktion BÜNDNIS 90/DIE GRÜNEN is a very modern and new approach to an "old problem" – see next chapter for details

6.2 Cannabis Control Act

Cannabis Control Act (CannKG) – a bill of the Fraktion BÜNDNIS 90/DIE GRÜNEN

A draft of a cannabis control act was presented to the German Bundestag by the Parliamentary Group of BÜNDNIS90/DIE GRÜNEN on 20th March 2015 (Cannabiskontrollgesetz, 2016).

The public hearing - Committee of Public Health – took place on the 16th March 2016 (Health, 2016).

The bill legalizes cannabis for recreational use for adults (age of 18 years). The possession of 30 g cannabis and cultivation of three female plants is allowed for adults with the obligation to ensure the protection of minors. According to this bill cannabis will be available in special shops that are authorized for cannabis retail.

The commercial dealing with cannabis requires a license that applies to retail, the purchase and sale of cannabis for purposes of wholesale trade, the import and export of cannabis, processing of cannabis, transportation of cannabis and the commercial cultivation of hemp for the production of cannabis. The complete commercial chain is regulated and controlled including a specified reporting and documentation system.

The Cannabis Control Act **does not apply** to for **medicinal** purposes and has no effect on the approval procedure of varieties and seed transport within the meaning of the Seed Transport Act.

Justification for the Bill acc. to BÜNDNIS 90/DIE GRÜNEN

The following arguments are provided as justification for the legislative initiative:

- Failure of drug policy based on prohibition
- Failure of protection of minors: consequence of the current restrictive drug policy, lack of educational programs and strengthening of black marketing strategies are seen as major reason failure of protection of minors. The intended benefit of the ban of cannabis is turned into the opposite considering that young people are more likely to take risks and the attraction of what is forbidden.

- Effective consumer protection and harm reduction is hindered by illicit trade, black market and internet retail. The quality and purity of cannabis and cannabis containing products are not controlled, so content of active ingredient or contaminations remain dubious.
- Cannabis is the most commonly used illicit drug: Estimated cannabis consumption is 2.3 million adult citizens in Germany, making cannabis to the most commonly used illicit drug.
- The majority of adult consumers and consumers practiced no risky use of cannabis and the current legal situation leads them to a disproportionate criminalization. Compared with other licit substances such as alcohol and tobacco this is considered as a disproportionate interference with their freedom of action.
- The Federal Constitutional Court has acknowledged 1994 “Cannabis-Decision“ (BVerfGE 90) the possibility of a limited criminal liability of the acquisition and possession of small amounts of cannabis to the occasional consumption.

This drafted law regulates the handling of cannabis, in particular possession, cultivation, processing, transportation, Retail, wholesale, import and export of cannabis. In addition, this law regulates the use of cannabis for scientific purposes and the cultivation of industrial hemp as well its protection against abuse. Licensing and supervision of approved dealing with cannabis lies under responsibility of the competent authority designated by the Länder government. The main customs offices are responsible for the control and monitoring of the import and export of cannabis. Trade, farming and import of genetically modified hemp and cannabis is prohibited (§ 8). The scientific use of cannabis has to be notified to the designated Länder authorities that also have the control function. The Federal Agency for agriculture and food monitors and approves the cultivation of industrial hemp.

Consumer and health protection

The bill includes a social concept and a chapter dedicated to consumer and health protection. This includes protection measures from exposure to cannabis smoke/vapor in indoor workplaces, public transport and buildings, similar to tobacco non-smoker protection.

Labeling requirements

- Package inserts explaining to the consumer the ingredients, concentration, risks and possible undesired effects
- On the packaging, the following warnings have to be applied: "For adults only. Keep out of reach of children and young people. " , "the use of cannabis can lead to a dependence and other health problems”
- “Children and adolescents can be impaired by the use of cannabis in their development”
- “Contact your doctor or the nearest drug counseling Office for problems. "
- "you should not drive under the influence of cannabis “
- A warning notice in the form of a pictogram against the consumption of cannabis during pregnancy and lactation

The required details to be mentioned in the package insert resemble the mandatory information to be provided in a patient information leaflet of a medicinal product (compare with QRD template provided by EMA (EMA: QRD template, 2016). Details regarding qualitative and quantitative composition, special warnings and precautions for use, contraindications and interaction with other medicinal products, have to be provided. Additionally descriptions of the side effects that occur under normal conditions of use of cannabis and advise what to do in these cases, have to be added.

Dosage, type of application and duration as well as instructions in case of overdose have to be included in the package insert together with recommendations on tobacco-free and oral consumption and combustion-free forms of consumption.

The sales staff plays are prominent role as contact person and advisor a consumer can address to when questions or difficulties come up. The design of warning signs, leaflet and pictograms are according to paragraphs 2 and 3 set by the Federal Ministry of Health decree without the consent of the Federal Council.

Protection of minors

- Prohibition of direct and indirect advertising
- The prohibition of sales to minors
- Access control and proof of age
- Minimum distances of Cannabis shops from schools and facilities for young people

Cannabis shops

- Authorized for cannabis retail
- Minimum distances of Cannabis shops from schools and facilities for young people
- Trained personnel
- Employees have to acquire the certificate of responsible conduct of sales prior to the permission to sell cannabis
- Proof of good conduct (Führungszeugnis nach § 30 Absatz 5 Bundeszentralregistergesetz) is required
- Operators of cannabis shops have to assign and nominate officially a representative for the development of a social concept. This concept includes:
- Measures regarding the prevention of drug dependence
- The protection of minors
- The training of the sales staff

Road safety

The Cannabis Control act stipulates changes in the German Road Traffic Act (§ 24a StVG) by adding a threshold for THC: 5,0 ng/ml Delta-9-Tetrahydrocannabinol concentration measured in the blood. So far the threshold for THC content was below 1.0 ng/ml (3.3 Driving under the influence of cannabis). Package inserts explaining to the consumer "you should not drive under the influence of cannabis “

Penal provisions

The bill also regulates that it is punishable with a custodial sentence of up to three years or by a fine

- to own more than 30 gram if not entitled via special permission)
- selling cannabis to minors
- to cultivate more than three female plants or to store more than a years harvest of three plants
- to sell cannabis without permission or to sell contaminated cannabis

Reporting and Evaluation commitments

Annual report (due 30th June) is provided to the general secretary of the United Nations. The Federal Ministry of Health provides every fiur years an evaluation report to the German public and parliament. Every two years a report regarding the social concept has to be submitted to the relevant Länder authorities

Affected legal environment:

- The Cannabis Control Act stipulates a Cannabis tax – implementation via Cannabis Tax Act
- The German Narcotic Drugs Act (BtMG) including amendment of annex I-III.

In Annex I §1 abs. 1- Controlled drugs not eligible for trade, nor for medical prescription - the following positions shall be deleted:

a) Cannabis (marijuana, plants and parts of plants of the genus cannabis),
b) Cannabis resin (hashish, separate the plants belonging to the genus cannabis resin),
c) the exceptions a) to e) between "Cannabis" and "Cannabis resin and
d) Tetrahydrocannabinols and the specified isomers and their stereo chemical variants.

In Annex II §1 abs. 1 - Controlled drugs eligible for trade but not for medical prescription the following positions shall be deleted:

a) Cannabis (Marihuana, plants and part of plants plants of the genus cannabis) –

If they are intended for the manufacture of preparations for medical purposes

b) Delta-9-Tetrahydrocannabinol (Delta-9-THC).

In Annex III §1 abs. 1 - Controlled drugs that are eligible for trade and may be prescribed - the following positions shall be deleted:

Cannabis (Marihuana, plants and parts of plants of the genus Cannabis).

- Precursors Monitoring Act (Grundstoffüberwachungsgesetz)
- power of ordinance (Verordungsrecht) / driving licenses can be refused if cannabis abuse is suspected
- Road Traffic Act (Straßenverkehrsgesetz): It is an administrative offence to use a motor vehicle with measured serum concentrations of 5.0 ng/ml or more active delta-9-tetrahydrocannabinol (active THC)

6.3 The Cannabis Control Act – an innovative legal approach to an old problem

The Cannabis Control Act, aiming at legalization of cannabis for recreational purposes, includes provisions for handling, cultivation, processing, transportation, retail, wholesale, import and export of cannabis. This drafted law regulates the use of cannabis for scientific purposes and the cultivation of industrial hemp as well its protection against abuse. The protection of consumers and minors is addressed, labeling requirements, retail via specialized Cannabis shops. This bill has been carefully thought through. It provides legal clarity and harmonization as it defines e.g. in all federal Länder harmonized thresholds. The bill focusses not on the medical and pharmaceutical aspect of the consumption of cannabis but on the social aspects including the damage that is done to the society via illicit drug trafficking, acquisitive crime or violence and money laundering.

Social reality is a step ahead of mere punishment and mandatory law enforcement. There are already measures implemented in jurisdiction that aim to help rather than to punish. Drug consumption rooms (chapter 3.2 and “Therapy instead of punishment” in chapter 2.3.1) have to be named here. And these are strategies to help people who are addicted to substances that bear a higher risk than cannabis consumption. The thresholds for cannabis, despite diverging considerably within Germany, are another

example that the possession of small amounts for own consumption is not considered as illegal. The Green Party and Bündnis 90, the originator of this bill, argue that a general regulation, valid throughout Germany, would provide overdue legal clarity.

The Cann KT bill may be are a political and moral challenge, but it takes the actual situation in Germany into account, including the Länder initiatives to legalize cannabis (chapter 4, legal expert statements (LEAP, Schildow circle) and growing malaise in public opinion. Therefore it is not surprising that the Green Party and Bündnis 90, the originator of Cann KT, have supporters in left wing parties (e.g. Die Linke) and in legal experts groups e.g.: LEAP, Schildow circle, chapter 4, and The New Association of Judges (Neue Richtervereinigung, 2016).

Dr. Peter Cremer-Schaeffer, head of the Federal Opium Agency rejects a liberalization of drug policy regarding cannabis. He argues in his book "Cannabis. Was man weiss. Was man wissen sollte" (Cremer-Schaeffer, 2016) that the risk to public health, especially that of adolescence, is too high and that he sees, in contrast to others, that the prohibition based policy showed success in Germany. Marlene Mortler, the German Federal Drug Commissioner and Federal Health Minister, Herrmann Gröhe, despite in favor of cannabis for medicinal purposes, reject the legalization of cannabis for recreational use, pointing to health risks (chapter 4).

7 New psychoactive substances a challenge to modern society

New psychoactive substances (NPS) pose a growing risk to public health. Seizures as well as documented increase in the need for treatment due to health and psychological problems after the consumption of NPS confirm the growing risk. These drugs have been created to evade drug laws and have the potential to pose serious risks to public health and safety and can even be fatal.

NPS can be categorized into five major groups based on the similarity of the parent compound: (1) cocaine, amphetamines and ecstasy; (2) cannabinoids; (3) benzodiazepine based drugs; (4) dissociatives similar to ketamine and phencyclidine (PCP); and (5) those similar to hallucinogens such as LSD and psilocybin (David Baumeister, 2015).

7.1 Synthetic cannabinoids

Synthetic cannabinoids derivatives are often among the new substances detected for the first time in 2015 and reported to the EU Early Warning System EWS (chapter 7.2), twenty-four of 98 were synthetic cannabinoids. Synthetic cannabinoids mimic the effects of delta-9-tetrahydrocannabinol (THC): Synthetic cannabinoids attach to the cannabinoid receptors (CB1 or CB2) in the brain (cell membrane receptors mediating typical effects occurring after cannabis use.

Herbal Incense, Herbal Blends, "Spice" Products: herbal incense or herbal highs are sold with catchy brand names like "Spice", "Jamaican Gold", "Monkees go Bananas", "Black Mamba" or "Lava Red". Synthetic cannabinoids are applied to mixtures of plant materials acting as carriers and consumption way is usually inhaling: smoked in a cigarette, in a pipe or a bong, similar to cannabis. After smoking, onset of action usually occurs within a few minutes (acc. to brochure on synthetic cannabinoids (EU-Project "SPICE and synthetic cannabinoids" (Auwärter, 2016)). One problem is the insufficient or misleading labeling. The ingredients listed on the packets do not reflect the actual composition and sometimes synthetic cannabinoids are even labelled as "not for human consumption".

Information panel 4 Origin of synthetic cannabinoids

Origin of synthetic cannabinoids

In the 1980´s cannabinoid compounds were developed in the context of multiple sclerosis, HIV/AIDS, and chemotherapy research. John William Huffman (born 1932) a professor (now emeritus) of organic chemistry at Havard and his team developed over 400 synthetic cannabinoid substances which were used to test the effect of cannabinoid receptors in the brain and other organs. Other chemical engineers/ companies also developed THC analogues. Their comparatively easy synthesis process helped to spread the substances in an unintentional way. The pharmaceutical development wasn´t continued – their heritage of intoxication and illegal drug production remain (Wikipedia, 2016); (Ernst L, 2012)

The synthetic cannabinoids originated from the laboratories of John W. Huffman (JWH compounds), Pfizer Inc. (CP compounds), Hebrew University (HU compounds), and Alexandros Makriyannis (AM compounds) can be distinguished by their and consist of seven distinct structural groups: naphthoylindoles, naphthylmethylindoles, naphthoylpyrroles, naphthylmethylindenes, phenylacetylindoles, cyclohexylphenols, and classical cannabinoid. (Ernst L, 2012)

The psychotropic effects are similar to those of cannabis but pharmacological profiles of synthetic cannabinoids differ from THC. At first sight, side effects seem to be similar but due to higher potency and toxicity the health related problems are more severe: Synthetic cannabinoids can cause e.g. increased heart rates, raised blood pressure, vomiting, psychotic episodes, panic attacks, convulsions and may damage organs. The knowledge of acute toxicity and long-term toxicity of synthetic cannabinoids is limited yet reported severe intoxications are clear indicators for their harmful properties. According to European Drug Report 2016 mass poisonings and deaths have been reported in connection with synthetic cannabinoid e.g. MDMB-CHMICA abuse resulted in 13 deaths and 23 non-fatal intoxication (EMCDDA European Drug Report, 2016), (EMCDDA, 2016).

Synthetic cannabinoids - and consumption of cannabis

Since synthetic cannabinoids are used as a substitute for cannabis, the availability and quality of cannabis also seem to play a major role for the prevalence of ‘Spice’ products (Auwärter, 2016). Easy access and the belief that synthetic cannabinoid products are based on natural/ herbal ingredients and hence can be considered as harmless may also have contributed to their use among young people. Additionally commonly used drug screenings do not detect use of synthetic cannabinoids. According to surveys, seeking a new “high” experience and the non-detectability were seen as an important advantage over cannabis (Erik W. Gunderson, 2014).

In 2014, 101 new psychoactive substances were reported for the first time in the EU, compared with 41 in 2010. More than 450 are currently being monitored by the EMCDDA. The production of such substances, including tableting, packaging and labelling, is increasingly handled inside the EU, but they are also imported. EU Member States report that China was the main source of NPS delivered to Europe in 2014 (EMCDDA, Report from EC and parliament and council on progress in the EU's 2013-2020 Drugs Strategy and 2013-2016 Action Plan on Drugs, 2015).

Information panel 5 "legal highs" and the role of the internet as source of supply

Sale of "legal highs" and the role of the internet as sources of supply

The use of "legal highs" has risen considerably among young people in the EU, according to data from "Eurobarometer", a study on young people and drugs (European Commission, 2016). The question is how can young people get access to these substances?

According to the Flash Eurobarometer 2011 (EU Commission, Flash Eurobarometer, 2016) 54% of young people who were asked about their experiences with NPS responded that a friend had offered them such substances, a third (36%) were offered such substances at a party or bought it in specialized shops. Less than a tenth (7%) had bought NPS via the Internet. These figures reflect that the internet plays only a minor role for retail or purchase for private use. Yet, the internet plays a pivotal role for the wholesale trade. According to data from Eurojust and Europol more than half of the EU countries specifically targeted drug-related crime over the internet. In Germany the Federal Criminal Police Office (BKA) detected an increase of narcotic trade of all kinds via the Internet with a focus on synthetic drugs. In addition the trade with drugs shifts increasingly from the clear web in the darknet. The darkweb or darknet refers to websites that are not openly available on the internet, and require specific software to access. Therefore anonymization and encoding makes the identification of administrators, vendors and customers even more difficult and virtual currencies, such as Bitcoin, offers anonymity for the users (Council of the European Union, 2016). Products seem to be sold in a "stepwise system". Sellers do not always advertise all their products openly. If a more intense contact with customers has been built up the variety of offered substances widens (Home Office UK - The New Psychoactive Substances Review Expert Panel , 2016). Payment methods include bank transfers, E-money and virtual currencies.

China and India, are the main distributors. Wholesale web shops offer named chemicals either 'off the shelf' or synthesized to order. The bulk importation of NPS is often done via mail and fast parcel services. Materials are then distributed further by online as well as offline retailers or private contacts (Home Office UK - The New Psychoactive Substances Review Expert Panel , 2016).

7.2 Detection of new substances, warning systems and reporting ways

April 2016 the United Nations General Assembly at the Special Session on the world drug problem (UNGASS, 2016) adopted recently a resolution "Our joint commitment to effectively addressing and countering the world drug problem" (UNGASS, 2016) with a section dedicated to NPS. The joint commitment calls for strengthening action to address the challenge of NPS as well as for enhancing information-sharing and early warning networks.

EU Early Warning System

Since 1997, the EMCDDA main responsibilities is to operate the EU Early Warning System (EWS), with its partner Europol. The EWS works by collecting information on the appearance and spread of new substances from the 30 national early warning systems (including 28 Member States, Turkey and Norway) reporting to the EMCDDA and initiates risk assessments of new substances when necessary.

Information panel 6 Reitox, National focal points, German contribution

Reitox, National focal points, German contribution

Reitox (Réseau Européen d´Information sur les Drogues et les Toxicomanies) is the European information network on drugs and drug addiction. The responsibilities of the Reitox **national focal points** in the EMCDDA are addressed in the Recast Regulation (EC) No 1920/2006 of 12 December 2006. Reitox directly contributes to the EMCDDA's main task of collecting and reporting information on drugs and drug addiction in Europe. Each EU Member State (28 EU member states plus Norway, the European Commission and candidate countries or other participating countries) established/designated one national focal point (NFP) that built an information network. NFPs participate in the Early warning system and report to the EMCDDA. They collect, analyze and evaluate data and report the results at national level as well as to the EMCDDA.
The **reporting system** is based on five key epidemiological **indicators**: 1 general population surveys including youth surveys, 2 problematic drug use, 3 treatment demand indicator, 4 drug related deaths and 5 drug related infectious diseases. NFPs are also engaged in improvement and harmonization of data collection methodologies and develop their own guidelines. (EMCDDA: Reitox and function of NFP, 2016). The Reitox network does not only collect data to monitor the drug situation in Europe but also controls the success of EU drugs action plans. These data are the basis for the development of recommendations and EU drug policies.

German national focal point (NFP): The German Ministry for Health nominated the Federal Centre for Health Education (Bundeszentrale für gesundheitliche Aufklärung, BZgA in Cologne), the German Centre for Addiction Issues (Deutsche Hauptstelle für Suchtfragen e.V., DHS in Hamm) and the IFT Institute for Therapy Research (IFT Institut für Therapiefoschung in Munich).

The three institutions constitute the **German Monitoring Centre for Drugs and Drug Addiction** (DBDD). The IFT is responsible for the management of the NFP. The institutes have core responsibilities within the DBDD: the BZgA focusses on prevention aspects, the DHS on the addiction treatment and harm reduction, and the IFT is responsible for epidemiology, drug policy and legal framework, information on drug-related harms, including addiction treatment and harm reduction. The IFT coordinates the German Early Warning System and addresses emerging NPS as well as alarming developments. The current German representatives within the EMCDDA are Marlene Mortler, the German National Drug Commissioner, Professor Dr. Gerhard Bühringer (IFT Munich, University of Dresden, Chair of the Scientific Committee) and Professor Dr. Rainer Spanagel (ZI Mannheim), members of EMCDDA's Scientific Committee (EMCDDA: NFP overview, 2016).

When a new psychoactive substance is first detected, available information (manufacture, trafficking and medical use) is sent by the EU Member States to the EMCDDA in Lisbon and to Europol in the Hague via the REITOX national focal points and the Europol National Units. Reporting lines: EMCDDA and Europol collect the information and communicate it to the representatives of the Reitox network of the Member States and the Europol National Units, to the European Commission and to the London based European Medicines Agency (EMA) (EMCDDA: Early Warning System, 2016). EMA provides data to Europol and the EMCDDA regarding a potential marketing authorization existing, expired or applied for (EMCDDA: EWS operating guidelines, 2016).

A Joint Report is provided that includes

- Definition of the NPS: a chemical and physical description, including trivial name
- Frequency, circumstances and/or quantities encountered (e.g. seized)
- Manufacturing methods / chemical precursors
- Involvement of organized crime in the manufacture
- Trafficking

Additionally information is provided regarding expected use, health and associated social risks and if the NPS is currently subject to control measures at national or international level.

Based on the Report, the Council, can request a risk assessment of the health and social risks, caused by the use, manufacture and traffic of a new psychoactive substance, the involvement of organized crime and possible consequences of control measures.

Mutual information network including EWS – still developing

The current EWS system is based on Council Decision 2005/387/JHA. A recent legislative initiative (COM(2016) 547, 2016/0261 (COD) 29.8.2016 Proposal for a Regulation of the EP and the council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances) focusses on the strengthening of the EWS regarding risk assessment and streamlining procedures to ensure more effective and fast action. It is foreseen that the EMCDDA develops better collaboration with Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority and plans the participation of EUROPOL regarding involvement of criminal groups in the manufacture and distribution of NPS.

The aggravating drug problem discussed during United Nations General Assembly at the Special Session on the world drug problem (UNGASS, 19-21 April 2016) provoked a reconsidering of legislative strategies. EU proposals for amendments of regulation on new psychoactive substances had been pending (chapter 7.5) and now, legislative activities are resumed. One example is the proposed amendment of the efficacy of EWS (COM(2016) 547).

7.3 Definition – What are legal highs and what is so problematic about them?

The so-called "legal highs" are unregulated psychoactive products, NPS, as addressed in previous chapters. “Legal highs” are often sold via the Internet and advertised with aggressive and sophisticated marketing strategies. These substances are legal, because they have not yet been classified under the respective regulations: either because they have not been identified up to now (see process of EWS above) or the procedure to classify them under the narcotic drug act is ongoing (chapter 7.4).

The courts in Germany and in the EU had just recently to deal again with the unclear legal situation of these substances. Federal Court Germany (Bundesgerichtshof BGH) had to decide in two appeal procedures whether the sale of mixtures containing synthetic cannabinoids used as a marijuana substitute “may give rise to criminal law proceedings based on unlawful sale of unsafe medicinal products.” Two vendors of mixtures containing synthetic cannabinoids had been convicted of the sale of **unsafe medicinal products** by lower German courts. At the time of the court decisions substances in question did not fall under the BtMG, so that the German authorities were unable to apply criminal law proceedings on the basis of the BtMG.

7.3.1 "Legal highs" are not medicinal products

The Court of Justice of the European Union in Luxembourg, confirmed 10th July 2014 that under EU law the term "medicinal product" does not include substances such as mixtures of herbs containing synthetic cannabinoids. These substances have the effect of simply modifying physiological functions but have no beneficial effects on human health, neither immediately nor in the long term, (Judgment in Joined Cases C-358/13 and C-181/14 (Court of Justice of the European Union, Luxembourg, 2016).

Court's response to the questions submitted by the BGH provided a clear interpretation of the **concept of 'medicinal products'(**Information panel 7 Definition of the term 'medicinal products'**)**. The consumption of synthetic cannabinoids was not for therapeutic but for purely recreational purposes. The court stated that these psychoactive substances induce a state of intoxication and often also cause side effects like nausea, vomiting, heart-racing, disorientation. First synthetic cannabinoids can be traced back to pharmaceutical developments (Information panel 4 Origin of synthetic cannabinoids). The development was ceased because desired health effects could not be achieved and considerable side effects were foreseeable due to the psychoactive effects. The Court refers to the definition of a 'medicinal product' as it is provided in Article 1(2)(b) of Directive 2001/83/EC (refer to chapter "Definition of a medicinal product") and states that these substances cannot be classified as medicinal products.

A legal loophole does not justify legal tactics: if the court´s decision means that due to a gap in legislation the marketing of these substances is legal ("legal highs"), it is legal – until evidence and data are provided to be able to bring them under the auspices of the narcotics regulations. The process is explained in chapter 2.2 Procedures to amend annexes of BtMG. This situation makes it clear that in Germany as well as in Europe there is an urgent need for a rapid and effective process to regulate these substances.

Information panel 7 Definition of the term 'medicinal products'

Definition acc to. Article 1(2)(b) of Directive 2001/83/EC

The term '**medicinal product' is defined**, in Article 1(2)(b) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2011on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31st March 2004 (OJ 2004 L 136, p. 34). Under that provision, a medicinal product is defined as 'any substance or combination of substances which may be used in or administered to human beings with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis'.

Definition acc. to. § 2 German Drug Act (AMG)

Medicinal products are substances or preparations made from substances which

1. are intended for use on or in the human or animal body and are intended for use as remedies with properties for the curing, alleviating or preventing of human or animal diseases or disease symptoms or
2. can be used in or on the human or animal body or can be administered to a human being or an animal, either: to restore, correct or to influence the physiological functions through a pharmacological, immunological or metabolic effect, or b) to make a medical diagnosis.

7.3.2 Race between hedgehog and hare

The consumption and supply of NPS has spread rapidly in Germany (as in other EU Member States) in recent years. These substances are often very similar in terms of their chemical structures compared with those already included in the annexes of the BTMG. The same applies to synthetic Cannabinoids. The frequent change of compositions and substances by manufacturers and traders makes it difficult to assess, monitor and control the supply of these products. Given that the new substance is similar to the already subordinated substance in terms of structure and effect, the potential for abuse due to its assumed legality is exploited.

The authorities and law-makers are facing a "race with chemists" who are producing potentially dangerous new "legal highs" on a weekly basis (Norman Baker, British Home Office minister, 2016). It is almost impossible to keep up with the chemists designing new chemical compounds to bypass the legislative system. The situation resembles the Race between hare and hedgehog in Grimm´s Märchen.

In the press release on the occasion of 28th Ordinance amending provisions of narcotics legislation, that banned 32 new psychoactive substances, Marlene Mortler, the German Federal Drug Commissioner, confirmed the necessity to ban the substances but also considered the increasing pace of their occurrence (Mortler, 2016). This race between occurrence of a new chemical variant and its prohibition is currently determined by the speed of detection, definition and subsequent scheduling under the annexes I to III BtMG.

7.4 Current procedure to add NPS to annex I to III of the BtMG - BtMÄndV

The procedure to bring NPS or "legal highs" under the auspices of the German narcotics drug regulations is to add them to annexes I to III of the BtMG by Betäubungsmittelrechts-Änderungsverordnung (BtMÄndV, chapter 2.2). The Committee of Independent Experts acc. to § 1 abs. 2 BtMG advises the government and provides scientific recommendations regarding these substances.

Recently the Thirty-First Ordinance amending provisions of narcotics legislation (Thirty-First Narcotics Legislation Amendment Ordinance 31. BtMÄndV 2016/48/D (Germany) came into force. Responsible department: Bundesministerium für Wirtschaft und Energie, Berlin, Originating Department: Bundesministerium für Gesundheit, Bonn (Bundesministerium für Gesundheit, 2016)

Six new psychoactive substances, a synthetic phenethylamine derivative and five synthetic cannabinoids are subject to this ordinance. They are included in Appendices I and II to the Narcotics Act. These substances were considered as hazardous by the competent German authorities and were recommended for inclusion under the Narcotics Act by the Experts' Committee on Narcotics pursuant to § 1(2) BtMG.

In the comment to 31. BtMÄndV 2016/48/D it is stated that these new psychoactive substances are mostly synthesized via chemical transformation (derivatization) of substances already included in the Narcotics Act. They exhibit similar risk profiles and in other EU Member States, these substances have already been brought under the auspices of their respective narcotics regulations.

Presence of these substances on the German market has been proven by seizures and treatment of patients who tried these new substances. The consumption and supply of NPS has spread rapidly in Germany (as in other EU Member States) in recent years – particularly among young people. Furthermore, consumers are either insufficiently informed, or not informed at all, about the ingredients

of the products offered and their health risks, as most manufacturers and distributors do not declare the ingredients.

7.5 European approach: Regulation of the European Parliament and of the Council on new psychoactive substance

There is general agreement upon the main shortcomings of the current control of illicit drugs: the slow and reactive evaluation process that focusses on single substances (EMCDDA, Europol 2011). Considering the rapid developments in NPDs and the lack of scientific evidence for the risks of these substances, the Commission called for an effective legal instrument to be able to control NPDs, including a temporary ban (European Commission EC) The Commission has committed itself to work on a legislative package on drugs, proposing the revision of the Council Framework Decision on drug trafficking and the Council Decision on new psychoactive substances including drug precursors, confiscation and recovery of criminal assets and on strengthening collaboration and mutual recognition, as well as measures to combat money laundering

The proposal COM/2013/0619 final - 2013/0305 (COD) for a regulation of the European Parliament and of the Council on new psychoactive substances is part of the new European legislation strategy to face the threat of illicit drugs. The planned regulation will replace Council Decision 2005/387/JHA.

The objective was to reduce the availability of new psychoactive substances that pose risk through swifter, more effective action on Union level compared to the currently applicable system based on Council Decision 2005/387/JHA

April 17th 2014, the plenary adopted 51 amendments in the report of the Committee on Civil Liberties, Justice and Home Affairs (European Parliament legislative resolution of 17th April 2014). The Proposal including the amendments from the outcome of the European Parliament's first reading in Strasbourg in summary:

- The legislative approach as such will be conceptually evaluated : individual substance approach/ groups of substances/ generic approach
- NPS have to considered as legitimate as long as not otherwise defined
- Urgent action procedure is foreseen for certain new psychoactive substances that pose immediate public health risks. Their availability should be restricted for a sufficient period of time until the level of risk has been determined and, if necessary, a decision regarding permanent market measures has entered into force
- New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development. This should be controlled by authorized persons in establishments which are directly under the control of Member States' authorities.
- The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) established by Regulation 1920/2006/EC of the European Parliament and of the Council of 12 December 2006 should have a central role in the exchange and coordination of information on new psychoactive substances.
- Confirmation and strengthening of the 'European Union Early Warning System (chapter 7.2) and Europol
- Commitment to pay special attention to the protection of children and adolescence

- Collaboration and information exchange among Member States is essential: If a Member State has information relating to a NPS, its National Focal Points within the European Information Network on Drugs and Drug Addiction (Information panel 6) and Europol national units shall report to EMCDDA and Europol. The EMCDDA and Europol request information from the European Medicines Agency (EMA) if the suspected NPS is an active substance in a human or veterinary medicinal product with a marketing authorization granted or applied for. The EMCDDA also cooperates with the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority regarding information and data at their disposal on the NPS
- Replacement of Decision 2005/387/JHA

Status, details and legislative procedure

The Proposal for a regulation of the European Parliament and of the Council on new psychoactive substances from the 17.09. 2013 and the Proposal for a Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug.

The legislative process: COD - Ordinary legislative procedure (ex-codecision procedure)
Status: Legislative proposal COM(2013)0619 was published 17.09.2013, debate in Council (28.01.2014, 13.03.2014 committee report tabled for plenary, 1st reading, 17.04.2014 decision by Parliament, 1st reading/single reading, 05.02.2015 opening of interinstitutional negotiations after 1st reading in Parliament, 14.09.2015 debate in Council (acc. to Procedure file 2013/0305(COD))

Negotiations of this legislative package have been ongoing for years. The European Parliament adopted its legislative resolutions on 17th April 2014 **but the Council did not adopt a general approach on the proposals**.

The legislative activities have been recently resumed and the proposal COM(2016) 547 2016/0261 (COD) from 29.08.2016 for amendments of Regulation (EC) No 1920/2006 as regards information exchange show that the issue has been re-prioritized. But meanwhile national legislative initiatives have been started as feared according to published conclusions of the council.

In December 2011, the Council of the European Union published conclusions on new psychoactive substances. These conclusions include the awareness that member states already started legislative initiatives and if the European Union does not take actions now the legal situation becomes increasing diverse and confusing (Council of the European Union - conclusions on new psychoactive substances (Council of the European Union, 2016)). **The German government refers to the right to enact further-reaching prohibition** and penal provisions on NPS trafficking because the above mentioned legal framework is not considered as sufficient.

7.6 German approach: New Psychoactive Substances Act (NPsG) - Act combating the dissemination of new psychoactive substances

In the past illicit trafficking in NPSs have been dealt with on the basis of the Medicinal Products Act (AMG). In the ruling of the Court of Justice of the European Union (CJEU) of 10th July 2014 (joined cases C-358/13 and C-181/14, see chapter 7.3.1), according to which the NPSs cannot be considered

under the definition of a medicinal product (Information panel 7 Definition of the term 'medicinal products'). The legal loophole for NPSs that have not yet been incorporated into the appendices to the BtMG had to be closed. The idea is to include entire substance groups rather than individual substances.

The Federal cabinet has passed a new bill on 4th May 2016 banning new psychoactive substances, first reading of the draft in German parliament (Bundestag, 2nd June 2016), committee on health politics in the Bundestag (6th July 2016) held expert hearing on the bill (Bundesministerium für Gesundheit, 2016). Press release from 23rd September 2016 (Bundesgesundheitsministerium 2./3. Lesung NPS, 2016) publishes that the German parliament decided upon the NPsG in second and third hearing.

New Psychoactive Substances Act (NPsG) aims to combat the distribution of NPSs and thus restrict their availability as drugs and intoxicants. The ban includes trading, placement on the market, manufacturing, importing, exporting and transit, acquisition, ownership and the administering of NPS. Penal provisions cover the handling of NPS with a view to circulating them. Exempt from the ban are accepted uses for commercial, industrial or scientific purposes (§ 3(2) NPsG) and the act does not apply for medicinal products and narcotics (§ 1(2) NPsG). Although medicinal products and narcotics are excluded their chemical by-products (derivatives) can be covered by this Act.

The two groups of substances of NPS which are subject to the ban are listed in an appendix: compounds derived from 2-phenylethylamine (including cathinones) and Cannabimimetic agents / synthetic cannabinoids. With respect to the dynamics of the emergence of further NPS, it is planned that this Appendix can be modified by means of a statutory instrument (Bundesministerium für Gesundheit, 2016), (Communication from the Commission - TRIS/(2016) 00767 - NPSG, 2016).

Information panel 8 Modular definition of affected NPS in annex of NPsG

Synthetic cannabinoids ("spice" ingredients) and 2-phenethylamine derivatives have been manufactured and distributed with minor modifications. It is predicted that substances with minor chemical changes that will appear on the market in the future may also pose a risk to public health. Based on this assumption the annex of the NPsG lists derivatives of these two substances:

1. Compounds derived from 2-phenethylamine:

   2-phenethylamines consist of phenyl residue, a hetrocyclic or polycyclic ring system or an alkyl residue (structural element A) and a side chain with a nitrogen atom (structural element B), which can be differently substituted. Cathinones (2-Amino-1-phenyl-1-propanone) are subsumed under this substance group as beta-keto derivatives. In the literature, of the wider group of 2-phenethylamines (including amphetamines, cathinones, etc.), around 2 000 substances are described as having psychoactive effects. The 2-phenethylamine substance group described in the annex of NPsG has been restricted to substances for which there have been previous findings of misuse for intoxication purposes.

   Therefore, the structures of structural element A and the side chain substituents (structural element B) are limited to those that can be synthesized at relatively low cost using accessible starting chemicals and that lead to already described and tested structural variants. The authors of the bill refer to literature data and observations that showed that the suspected structure-activity relationship is confirmed for modified substances.

Information panel 8 continued

2. Cannabimimetics/synthetic cannabinoids:

   Cannabimimetics/synthetic cannabinoids can be constructed and described according to a modular design. These compounds have a core structure that is linked via a bridge to a bridge radical and this structure has a side chain in a defined position in the core structure. These four structural elements have varying significance for the binding affinity of the molecule to the CB1 receptor, which is mainly responsible for the cannabis-like psychotropic effect (as described for example in "The 'pharmacophore rule' and the 'spices' (Travis J. Worst, 2015). The core structure is particularly significant for receptor binding and hence for pharmacological effectiveness. Even small structural changes to the core structure can lead to a drastic reduction in psychotropic effectiveness. Therefore, when determining the substance group, the core structure is very accurately defined

   The cannabimimetics/synthetic cannabinoid substance group described in this Act significantly reduces the substitution possibilities for the four stated structural elements to varying degrees to schedule as many known psychoactive substances as possible and to exclude substances that are thought to be less effective.

   The bridge connects the core structure to the bridge radical. To optimize synthesis, it must ensure chemically simple coupling between the bridge radical and the core structure without affecting receptor binding. According to analysis of patents and the scientific literature, only a few relatively polar structures for potent cannabis-mimetics can be accurately designated. The bridge radical is the chemical structure with the highest variability, for which steric effects seem primarily to play a role, in addition to interactions with aromatic units. The bridge radical has only a minor impact on receptor binding as long as it does not fill up too much space.

   The size of the molecule matters because of the influence on availability of the molecule at the site of action and the ability to cross the blood-brain barrier.

   By restricting the substitution possibilities on the core structure, the narrow definition of the bridge, the molecular weight and chain length restrictions for the bridge radical and the restrictions on side chain substitution and length ensures that a considerable proportion of the individual substances included in the substance group definition is pharmacologically active.

To avoid contradictions with substances already scheduled in Annexes I to III of the BtMG and to avoid extending criminal penalties on restricted substances, individual substances that are psychoactive and dangerous to health and are also widely misused are listed in substance groups in the annexes to the BtMG. In these cases, the provisions of the BtMG prevail.

- Administrative prohibition on trafficking in NPSs includes: dealing; putting into circulation; manufacturing, importing, exporting and transiting; procurement; possession and administration of NPSs. The prohibition is linked to penal provisions.
- In the case of commercial or organized trafficking, crime telecommunications surveillance shall be allowed in order to track internet traffic in particular. In the case of commercial or organized trafficking, provisional detention of accused persons shall also be allowed to prevent the danger of reoffending

- NPSs may be confiscated as part of criminal proceedings and even stronger, to protect the public health the administrative prohibition extending beyond penal provisions allows the competent authorities to seize and destroy NPSs independently of criminal proceedings.
- Recognized uses for legitimate purposes of NPS are excluded from the prohibition.
- **Emerging NPS – inclusion procedure**: NPS substance groups that are subject to the prohibition are listed in the annex. This annex may be amended acc. to § 7 NPsG: The Federal Ministry of Health is empowered, by statutory instrument requiring the approval of the Bundesrat, in consultation with the Federal Ministry for the Interior, the Federal Ministry of Justice and Consumer Protection and with the Federal Ministry of Finance and after consultations with experts, to amend the list of substance groups in the annex.

7.6.1 Compatibility with European Union law and international treaties

The compatibility of this bill within the legal European and international framework is discussed in the following section.

NPsG - Notification procedure – information of the EU Commission

The bill combating the dissemination of new psychoactive substances 2016/121/D has been notified according to Directive 2015/1535 (chapter 5.3, Notification procedure). Thus the Commission has been informed about the legislative initiative. Any drafted technical regulation has to be introduced before its adoption in national law. After closure of the notification procedure the bill will be sent to the federal cabinet.

Notification Number: 2016/0121/D - C00C; date received: 10.03.2016, End of Standstill: 14.04.2016; Responsible department: Bundesministerium für Wirtschaft und Energie, Berlin, Originating Department: Bundesministerium für Gesundheit, Bonn.

Relevant European Union laws and international treaties

The German Act on new psychoactive substances (NPsG) is a reaction on the growing threat of new emerging substances. It takes recent legal developments into account (see above) but also the following European laws and international treaties:

The international conventions on narcotics (Single Convention on Narcotic Drugs of 1961, Convention on Psychotropic Substances of 1971, Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988) and European law (Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug trafficking)

7.7 NPsG: Legal options and pitfalls

Currently the national procedure to bring new psychoactive substances or “legal highs” under the auspices of the German narcotics drug regulations is to add them to annex I to III of the BtMG (chapter 2.2). For this purpose the substances are chemically characterized and their chemical properties are described and defined. The bill on NPsG provides a modular definition of affected NPS in its annex. It

thus includes compounds derived from 2-phenylethylamine (including cathinones) and cannabimimetic agents/synthetic cannabinoids. Other countries in Europe, the United Kingdom for example, have a different approach. They use a generic approach that includes as many substance/ derivatives as possible using categories of substances. The more substances captured, the better (chapter 7.7.2).

7.7.1 Generic approach is problematic in the German legislation

Currently it is not possible in Germany to add categories of substances to the narcotics legislation. In Germany individual substances have to be defined and actively included in the annexes of the BtMG. The introduction of generic legislation is problematic due to the following reasons:

- Principle of specificity acc. to German Constitution (Bestimmtheitsgebot für Strafgesetze aus Artikel 103 Absatz 2 des Grundgesetzes (GG)
- Compliance with German rule of law principle (Rechtsstaatsprinzip § 20 Absatz 3 GG)
- Sanctions and penalties have to be adequate. NPS are chemically diverse and belong to different substance classes.
- Not all NPS can be attributed to a particular substance group and thus need to be individually recorded (Jan van Amsterdam D. N., 2013)

At present the generic legislative approach would violate the constitutional principles – such as individuals should not be convicted of a crime (drug possession) without knowing that the substance has been banned. Therefore generic legislation from other states (see chapter 7.7.2) cannot be adopted without changing legal environment e.g. under consideration of the German constitutional principle of specificity (Bestimmtheitsgebot für Strafgesetze aus Artikel 103, Abs. 2 des Grundgesetzes see also (Bundesrat Drucksache, 2016))

Taking this into account the new bill had to be evaluated regarding its legal conformity.

Expert opinion on feasibility of the new act on NPS (Dieter Rössner, 2016) **confirmed the legal concept of two parallel regulations banning psychoactive substances and their legal conformity.**

- Because it cannot be ruled out that individual substances in a substance group lack a significant psychoactive effect, substance groups shall not be included in the BtMG. To ensure the principle of proportionality and the principle of liability (see above) NPS are not under the auspice of the BtMG but will be subject to the new NPsG. Substances with scientifically confirmed psychoactive properties posing a risk to public health, are listed in in the annexes to the BtMG.

The modular banning concept of the NPsG works under the assumption that the mode of action of scheduled substances can be predicted via their chemical structure. According to the **expert opinion on feasibility of the new act on NPS** (Dieter Rössner, 2016)**:**

- The modular banning concept of the bill is reasonable and justified based on the fact that the effect of NPS is mainly determined by the lead molecular structures that are responsible for receptor binding. Modifications by substituents or side chains can cause modifications of effect.
- It is acknowledged that the mode of action of these substances cannot always be accurately predicted via their chemical structure and that there is always an option that individual substances of a substance group have no significant psychoactive effect.
- Minor psychoactive effects does not mean that the substances in question are harmless. There could be other effects that pose a risk to health.

- Data have to be collected to gain information on possible and known chemical compounds to be able to estimate their pharmacological-toxicological effect and risk to public health. This re-evaluation is incorporated in the bill.

Federal Health Minister Hermann Gröhe stated: "with the far-reaching ban on new psychoactive substances we break through the space race between the occurrence of new chemical variants of known substances and it adapted interdictions in the narcotic drugs law finally. "So we give the clear signal: legal highs are forbidden and highly hazardous substances" (Drug commissioner & Ministry of Health, 2016).

The BtMG is very precise, the NPsG provides a modular definition and defines thus what substances are illegal. This is a more flexible but not a generic approach. Minister Gröhe is right, it is a measure against NPS and the bill would close a legal loophole when it comes into force. The question is: Is the German approach fast enough?

Looking at the most recent legal initiative in the United Kingdom reveals that other European countries have developed another concept:

7.7.2 Psychoactive Substances Act 2016 UK in comparison to the German NPsG

The Psychoactive Substances Act received Royal Assent on 28th January 2016. The act applies across the UK and is in force since 26th May 2016 (Psychoactive Substances Act UK, 2016).

The new British Psychoactive Substances Act 2016 makes it an offence to produce, supply, possess with intent to supply, possess on custodial premises, import or export **psychoactive substances; that is, any substance intended for human consumption that is capable of producing a psychoactive effect.** The maximum sentence will be 7 years' imprisonment**.**

The definition of "psychoactive substance" that are subject to the new British Act is:

- *"any substance which is capable of producing a psychoactive effect in a person who consumes it, and is not an exempted substance."*

A "psychoactive effect" is defined according to the act as follows:

- *"a substance produces a psychoactive effect in a person if, by stimulating or depressing the person's central nervous system, it affects the person's mental functioning or emotional state;"*

The definition of "intake/consumption" is defined according to the act as follows:

- *"For the purposes of this Act a person consumes a substance if the person causes or allows the substance, or fumes given off by the substance, to enter the person's body in any way."*

Exempted substances:

- The act excludes legitimate substances, such as food, alcohol, tobacco, nicotine, caffeine and medical products from the scope of the offence, as well as controlled drugs, which continue to be regulated by the Misuse of Drugs Act 1971

- and it exempts healthcare activities and approved scientific research from the offences under the provision that persons engaged in such activities have a legitimate need to use psychoactive substances in their work

The British Misuse of Drugs Act 1971 includes four separate categories: Class A, Class B, Class C and temporary class drugs. Substances may be removed and added to different parts of the schedule by statutory instrument, provided a report of the Advisory Council on the Misuse of Drugs has been commissioned and has reached a conclusion, although the Secretary of State is not bound by the council's findings.

Class A includes heroin, cocaine, crack, MDMA ("ecstasy"), methamphetamine, LSD, DMT and psilocybin mushrooms

Class B includes amphetamine, cannabis, codeine, ketamine, methoxetamine and methylphenidate. Any class B drug that is prepared for injections becomes a class A substance.

Class C includes GHB, diazepam, flunitrazepam and most other tranquillizers, sleeping tablets and benzodiazepines as well as anabolic steroids.

Temporary Class includes 6-APB, 5-, 25C-NBOMe, 25B-NBOMe and 25I-NBOMe

In contrast to the German approach the British act forbids any substance that has a psychoactive effect if not exempted according to schedule 1. The German legislation works the other way round – if not listed - it is allowed. The more rigorous British system has its advantages with regard to the race between chemists and law enforcement.

Currently it is not possible in Germany to add categories of substances to the BtMG (chapter 7.7.1) and it is questionable if the British approach is at all feasible in the German constitutional state. Yet the German NPsG is a step forward. It includes a lot of compounds and their analogues and derivatives. Germany is able to react with accelerated speed now and the outcome of the race between occurrence of a new chemical derivative and its prohibition will show if this law is an overall success.

8 Discussion

Three different bills, three different approaches with one aim: ensuring public health and welfare.

- Legalization of cannabis for medicinal purposes: Bill 2016/0014/D amending the narcotics regulations and other provisions
- Legalization of cannabis for recreational purposes: The Cannabis Control Act
- An act combating the dissemination of new psychoactive substances: New Psychoactive Substances Act

All three bills aim to ensure the protection of minors, consumers and public health in general.

The legalization of cannabis for medicinal purposes aims to help severely ill patients. It has been designed to make sure that patients are not deprived of a therapy that may not cure but help to cope with the illness, and the costs of therapy with medicinal cannabis will be covered by statutory health insurance. Recent activities of the German Pharmacopoeia Commission and German DAC/NRF succeeded in new and updated monographs and procedure descriptions regarding *Cannabis sativa*. Projects like chromatographic methods for identification of different cannabis varieties, HPLC methods for identification of Cannabinoids show that pharmaceutical environment is preparing the medical revival of cannabis (chapter 3.6.3).

Taking into account that:

- Natural cannabis is already available over an exemption procedure: an exemption on the purchase of cannabis within the scope of a medically supervised and assisted self-therapy according to § 3 abs. 2 BtMG can be applied for at the Federal Opium Agency (chapter 3.6.4) – *Yes, the procedure is time consuming and the support of dedicated health care professionals is essential but the possibility already exists and with that the option to improve this process …*
- The first temporary exempt for self cultivation of cannabis was granted 30. September 2016 (BfArM: Ausnahmeerlaubnis Eigenanbau, 2016) – *demonstrating that this procedure works at* least *in principle*
- The number of patients that would currently benefit from the new law is comparatively small (chapter 5.4.3)
- The medical benefit of cannabis is discussed controversially (chapter 5.4)
- There are approved medicinal products available like Sativex

makes it clear that this bill does not only have a medical purpose. Reimbursement of an acknowledged therapy especially for fatal or life-threatening diseases can longer be refused anymore ("Nikolaus Urteil" in chapter 5.4.3).

Another important point is the self-cultivation of cannabis. The idea that a severely ill patient grows his own medicine in a country with one of the highest medical standards is bizarre. Additionally the home cultivation is connected to a lot of problems and requirements including:

- the question of quality of the cannabis,
- posology (how much THC does my plant/joint/preparation contain?)
- safety measures to protect minors and to make sure that an unauthorized person is not "just taking a bit", and on top of that
- reports including the verification of destruction of plants/parts …These are requirements that have been laid down in the exceptional exempt from the BfArM **(BfArM: Ausnahmeerlaubnis Eigenanbau, 2016)**.

Easy to be fulfilled in a pharmaceutical company, maybe, for a pharmacy – but for a severely ill MS patient? With the new law self-cultivation is not necessary anymore, since cannabis based therapy is legal and natural cannabis can be provided in pharmaceutical grade via the Cannabis Agency (BfArM).

Cannabis, medicine or drug ? – Cannabis, medicine and drug ?

The use of cannabis to relieve pain - the use of cannabis to ease tension - the use of cannabis to give pleasure - the applications are not diametrically distinct, rather flowing transitions.

The fear has been expressed that allowing natural cannabis (dried plant parts inhaled, smoked) as a medicine could blur the distinction between misuse and therapeutic use (Cremer-Schaeffer, 2016). The fact that pharmacists in Germany experienced a significant increase in demand for cannabis in the first half of 2016, it almost doubled in comparison to 2015 (Die Zeit online, 2016), feeds this concern. The (not yet passed) Cann KT bill is not applicable to medicinal cannabis (chapter 6), and the legalization of cannabis planned by the Ministry of Health (chapter 5.2) is exclusively for patients that have a substantiated need for such a therapy - yet, people are inventive and the sales figures could not really be explained. Making cannabis available for medicinal purposes is not necessarily a step toward legalizing its recreational use, but the acceptance of its medical use could in fact pave the way for its more generalized use. But does this possible development really have to be considered as a catastrophe - or is the German society in fact preparing for this – with a Cannabis Control Act?

The benefit of natural cannabis over medicinal products containing cannabis is disputed. The German Pharmacists and German Medical Association and drug commissions (chapter 5.4.2) (Bundesärztekammer u Arzneimittelkommission, 2016) stated that they do not see an advantage of natural cannabis over approved medicinal products and expressed doubts regarding the therapeutic efficacy and conformity of natural cannabis. The bill 2016/0014/D stipulates that patients receiving a cannabis based treatment have to take part in a research program. These concerns may be incorporated in such a research program helping to find out about efficacy and safety of natural cannabis in various indications.

Social reality: Fact is, cannabis is on the German market, and a considerable part of the society is using cannabis on a regular basis (chapter 1 and chapter 4). People buy cannabis on a black market, and there is no quality control for the available products. Cannabis consumption as such is a health risk (Cremer-Schaeffer, 2016) but leaving definition of quality to drug dealers, is definitely also a risk to public health. Another problem is the increasing in THC content in cannabis products and decrease of cannabidiol (EMCDDA perspectives, 2016). The herbal cannabis production is rising and shifting to Europe (EMCDDA European Drug Report, 2016). The growing competitive pressure has triggered a selection of cannabis varieties with stronger concentration of THC for hashish production (Alexis Goosdeel, 2016). The impact on health for consumers is under evaluation but is clearly another indicator for the need of quality control and this is also addressed in the Cannabis Control Act.

Medical benefit of cannabis – in controversial discussion

What makes cannabis based medicinal products or natural cannabis so interesting is the wide range of possible therapeutic effects they are claimed to have. Currently, cannabis and cannabinoids based therapy has been used for treatment ranging from cancer and epilepsy, different forms of pain therapy, sleeping disorders and thus valuable for palliative therapy, to depression and anxiety, from attention deficit/hyperactivity disorder (ADHD), cluster headaches and Crohn's disease to Tourette‘s syndrome (chapter 5.4. Review of German Medical Association)

The significance of clinical data has been subject to many discussions. Meta data analysis and reviews criticize that study results were not always unambiguous and had included often too small patient numbers. There is a general call for more reliable data gained via ICH conform clinical studies (Arzneimittelkommission der deutschen Ärzteschaft, 2016), (Cremer-Schaeffer, 2016) (Penny F. Whiting, 2015). Even in recent review publications of dedicated proponents of cannabis based therapy like Grotenhermen and colleagues the request for better data is expressed (Mikael A. Kowal, 2016).

Research activities in connection with cannabis often include rare diseases. I found the following scientific activities in orphan studies including treatment of glioma (Sativex), treatment of perinatal asphyxia (Sativex), cannabidiol for the treatment of Dravet syndrome and cannabidiol for the prevention of graft-versus-host disease.

Let´s hope and see for patients with rare diseases that the current legislative initiatives are the dawn for cannabis research.

NPS

One legal strategy does not fit all. What applies to a drug policy regarding cannabis does not have to work for other intoxicating substances such as New Psychoactive Substances. There is a general acceptance that there is no alternative to prohibition.

One mayor problem is to detect and define the substances to be able to react. The frequent change of compositions and substances by manufacturers and traders makes it difficult to assess, monitor and control these products. The EMCDDA operates the EU Early Warning System (EWS) together with its partner Europol. Each Member State participates in the information network via their national focal points (chapter 7.2). It is a gigantic effort – yet, showing how difficult the situation is.

The new NPsG is the German strategy to speed up the reactive evaluation process that focusses on single substances. Currently in Germany individual substances have to be defined and included in the annexes of the BtMG by means of BtMÄndV, chapter 2.2. NPsG works on a modular banning concept based on the fact that the effect of NPS is mainly determined by lead molecular structures that are responsible for receptor binding. The bill includes compounds derived from 2-phenylethylamine (including cathinones) and cannabimimetic agents/synthetic cannabinoids. Expert opinion on feasibility of the new act confirmed the legal concept of two parallel regulations regulating psychoactive substances (BtMG and NPsG). **The NPsG is a step forward. It includes many compounds and their analogues and derivatives. The future will tell us – if this new act will provide us with the required leading edge over the canny chemists…**

Editorial deadline: 25th October 2016

Redaktionsschluss: Die bis zum 25. Oktober 2016 verfügbaren Informationen wurden berücksichtigt.

9 Summary

Iris Bruchmüller (2016)

Cannabis for medicinal and recreational purposes and new psychoactive substances – Critical review of recent legal initiatives in Germany

The German society is confronted with an aggravating drug problem, and the call for a more efficient drug policy is getting louder- and the awareness that decades of prohibition did not show the desired success is growing. At the same time we face a revived appreciation for and interest in cannabis based therapy. German policymakers are tackling the situation with three new drafted laws:

- Legalization of cannabis for medicinal purposes: Bill amending the narcotics regulations and other provisions
- Legalization of cannabis for recreational purposes: The Cannabis Control Act
- An act combating the dissemination of new psychoactive substances: New Psychoactive Substances Act

Cannabis for medicinal purposes: Federal Health Ministry of Germany presented on January 8th 2016 a drafted bill amending the narcotics regulations with the purpose to enable the marketing and prescription of pharmaceutical-grade Cannabis to specific, particularly chronically and seriously ill patients. It postulates controlled access to pharmaceutical-grade cannabis dispensed by pharmacists. The Federal Institute for Drugs and Medical Devices (BfArM) will be assigned as competent authority, in charge of the control of the cultivation of medical Cannabis (state agency).

Cannabis for recreational purposes: The drafted Cannabis Control Act, aiming at legalization of natural cannabis for recreational purposes, has been introduced by Bündnis 90/ The Green party. This bill focusses on protection of consumers and minors by establishing a regulated, quality controlled cannabis retail system. The drafted Cannabis Control Act includes inter alia provisions for consumption, private cultivation, retail, wholesale, tax and import of cannabis. The special retail concept of this bill specifies that Cannabis is freely available for adults in specialized Cannabis shops.

In contrast to legalization initiatives for medicinal cannabis or decriminalization strategies for its recreational use, there is general consensus that new psychoactive substances (NPS) are harmful and that this growing problem requires special and intensified attention.

The New Psychoactive Substances Act is a new approach to ban these rapidly emerging substances. The Federal cabinet has passed a new bill on 4th May 2016 that includes trading, placement on the market, manufacturing, importing, exporting, ownership and the administering of NPS. Two groups of substances of NPS are subject to the ban: compounds derived from 2-phenylethylamine (including cathinones) and Cannabimimetic agents / synthetic cannabinoids, thus managing to capture and ban not only individual but analogues and chemical derivatives of scheduled compounds.

Pages: 58 Annex: -

10 Declaration/ Erklärung

Hiermit erkläre ich an Eides statt, die Arbeit selbstständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

Blieskastel, den 07.11.2016

Dr. Iris Bruchmüller

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