

Perspectives from a doctor's office in Germany

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This is the ACM and the IACM Office



This my medical practise

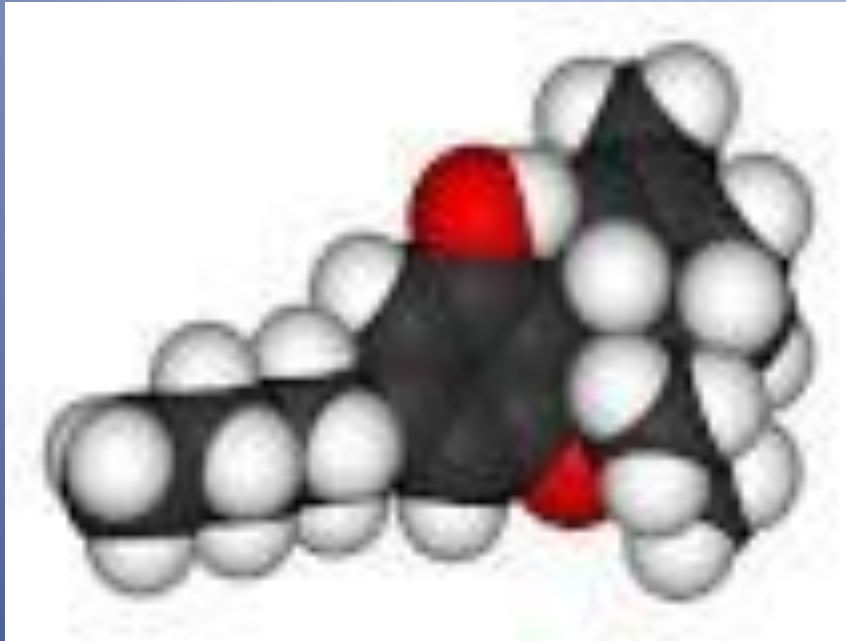


Possibilities of medical use in Germany

- In Germany cannabis-based medicinal drugs can be prescribed on a special prescription (THC/dronabinol, nabilone, Sativex).
- In addition, patients may apply to a body of the health ministry („Bundesopiumstelle“) for an exemption from the narcotics law to buy cannabis flowers from the pharmacy in the frame of a „doctor’s accompanied self-therapy“.

Prescription of cannabis-based-medicines

- All doctors of all specializations are allowed to prescribe dronabinol (THC), the synthetic THC-derivative nabilone and the cannabis extract Sativex for all medical conditions (off-label).
- Health insurances usually do not cover the costs. They only have to pay for a treatment with Sativex in spasticity due to MS.
- The monthly costs for a treatment with dronabinol, which is produced by two German companies with a mean daily dose of 10-15 mg is about 250 to 400 euros, for a treatment with Sativex with the same dose (4-6 sprays with 10.8-16.2 mg dronabinol) about 120-160 euros. Three bottles of Sativex cost 314 euros in Germany (810 mg THC and 750 mg CBD).



Dronabinol (THC), can be prescribed since 1998.

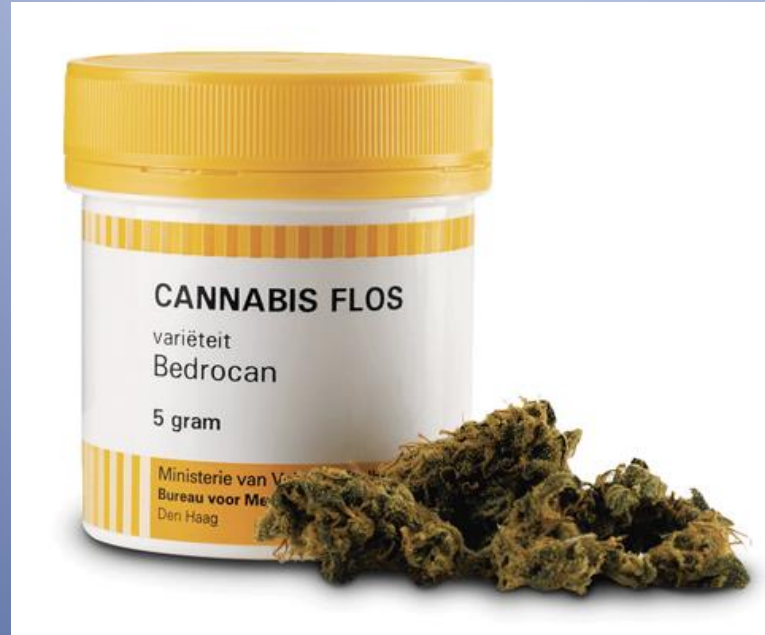




Cannabis spray **Sativex**, approved in Germany since 2011 for the treatment of spasticity in multiple sclerosis.

Treatment with cannabis with an exemption from the narcotics law

- As an alternative patients may apply to the Bundesopiumstelle, a body of the health ministry, for an approval for the acquisition for personal use of cannabis flowers in the frame of a doctor's accompanied self-therapy.
- In the application the patient has to explain that others treatments are not effective enough and a treatment with other cannabis medications is not possible since the costs are not reimbursed by the health insurance.
- A medical certificate has to be attached to the application.
- After approval patients can buy cannabis flowers produced by the Dutch company Bedrocan in a pharmacy, which has the approval to supply this patient with the medication.
- The cannabis flowers have to be paid by the patient. Depending on pharmacy costs are 14 to 25 euros a gramme.



Cannabis flowers of the company **Bedrocan** are available with an approval by the Bundesopiumstelle, a body of the federal health ministry.

Medical Conditions of patients with an approval to use cannabis flowers

- Acne inversa
- Allergies
- Anorexia and cachexia
- Anxiety disorder
- Asthma
- Attention deficit / hyperactivity disorder (ADHD)
- Autism
- Barrett's esophagus
- Bladder spasms (after multiple operations of the urogenital tract)
- Blepharospasm
- Borderline personality disorder
- Cervical and lumbar spine syndrome
- Cervicobrachialgia
- Chronic Fatigue Syndrome (CFS)
- Chronic pain syndrome after polytrauma
- Cluster headaches
- Condition after head injury
- Crohn's disease
- Dejerine-Roussy syndrome after stroke
- Depression
- Epilepsy
- Failed back surgery syndrome
- Fibromyalgia
- Headache
- Hereditary motor and sensory neuropathy with pain and spasms
- HIV infection

Continued

- Hyperhidrosis
- Irritable bowel syndrome
- Lumbago
- Lupus erythematosus
- Lyme disease
- Migraine
- Migraine accompagnée
- Mitochondropathy
- Multiple sclerosis
- Neurodermatitis
- Obsessive-compulsive disorder
- Osteoarthritis
- Painful spasticity in syringomyelia
- Paraplegia
- Paresis of the brachial plexus
- Paroxysmal nonkinesio gene dyskinesia
- Polyneuropathy
- Posner Castle Man Syndrome
- Post-traumatic stress disorder
- Psoriasis
- Restless legs syndrome
- Rheumatoid arthritis
- Sarcoidosis
- Scheuermann's disease
- Sleep disorder
- Spasticity in cerebral palsy
- Spondylitis ankylosans
- Still's disease
- Sudeck's dystrophy
- Systemic scleroderma
- Thrombangitis obliterans
- Tics
- Tinnitus
- Tourette's syndrome
- Trichotillomania
- Ulcerative colitis
- Urticaria of unknown origin

Why cannabis products are not the same medications as others

Cannabis products are not the same medications as others, because it is not sufficient to conduct large clinical trials for approval by the health authorities for 2, 5 or 10 indications to exploit the complete therapeutic potential.

Number of patients who receive cannabis-based medicines

- Currently about 10,000 patients receive a treatment with dronabinol or Sativex.
- About 500 patients receive a treatment with cannabis flowers. Last official number of July 2015: 463.
- There is a severe undersupply of the German population with cannabis-based medicines compared to Canada, the Netherlands and Israel.

Right on physical integrity

Federal Administrative Court 2005 (BVerwG 3 C 17.04):

- “The right of physical integrity cannot only be violated in that bodies of the state themselves produce an assault or inflict pain through their actions. The extent of protection of this fundamental right is also affected if the government takes measures to prevent a medical condition to be cured or at least be mitigated and thereby physical suffering is continued and maintained needlessly.”

Basic principles in Germany

The medical use of cannabis depend on two issues:

- Whether the patient has enough financial means to buy them.
- Whether the illness is treatment-resistant. Not whether the patient suffers from a certain disease on a list of indications. Such a list does not exist in Germany.

Case report 1: Restless legs syndrome

- A 28-year old man cannot remember a time without an urge to move his legs. Symptoms increased in the past two years resulting in pain and other symptoms. He is suffering from joint pain especially in the ankles, pain in the calves. He wakes up at night, is sleepy during the day and suffers from reactive depression. Over the past 2 years he had lost 45 kg.
- Initially a dopamine agonist (pramipexole) was tried for an initial period of 3 months, which however worsened the symptoms and was associated with side effects. Then he used levodopa for another 3 months, which was associated with abdominal pain, vomiting and loss of appetite.
- Cannabis caused a considerable improvement of all symptoms. He got an approval by the Bundesopiumstelle to use cannabis flowers in autumn 2014.
- He has two elder brothers suffering from the same condition, who refused to try cannabis, because it is an illegal dangerous drug. However, in July 2015 the second brother visited my practice after he had seen the improvement of his brother's condition and tried cannabis, which also worked for him.

Case report 2: ADHD

- Many so-called „neurodevelopmental disorders“ respond well to a treatment with cannabis products. These disorders include conditions such as attention deficit / hyperactivity disorder (ADHD), Tourette’s syndrome, obsessive-compulsive disorders and autism. With the exception of Tourette’s syndrome no clinical studies have been conducted so far.
- A 32-year old man was diagnosed with ADHD one year ago. Since childhood he suffers from difficulties to concentrate, anxiety and panic attacks. Later he developed depression and was treated for depression since 2008. He also suffers from an obsessive-compulsive disorder, currently mainly a compulsion to wash (ablutomania).
- When he was 16 he used cannabis for the first time and he felt “normal” for the first time. Only due to cannabis he was able to finish school. However, he had many problems with the law and psychiatrists, who diagnosed cannabis use disorders. He tried to explain the benefits of cannabis, but psychiatrists never believed him and his parents, who confirm that cannabis is very helpful in his condition. His family doctor supports a treatment with cannabis.
- He was prescribed methylphenidate, amphetamine and atomoxetine, which were associated with side effects and less effective than cannabis. Cannabis also improved depression and his compulsion.

Case report 3a: Acne inversa

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Acne inversa is a common, chronic skin disease characterized by clusters of abscesses or subcutaneous boil-like "infections" that most commonly affects apocrine sweat gland bearing areas, such as the underarms, under the breasts, inner thighs, groin and buttocks.

Case report 3b: Acne inversa

- A 43-year old man suffers from recurrent abscesses in the perianal, perigenital and inguinal region since 2002. Therapy was done nearly only by surgery, in part by opening single abscesses, in part by large-scale surgery. This often resulted in inability to work for 2-4 weeks. He also tried antibiotics, which was not very successful.
- In the year 2008 he tried cannabis, which was suggested to him by a friend, who suffered from another inflammatory skin disease. He took cannabis on a regular basis and found out that 10 grams per a month as a prophylaxis and a little more if he noted a beginning inflammation was sufficient to avoid abscesses completely. Between 2008 and 2013 there were no new abscesses. At the end of 2013 he had no sufficient access to cannabis products and he suffered from two new abscesses.
- He made an appointment in my practice because he was threatened to lose his driver's license, which he needs for his job. I prescribed Sativex, which was also effective, for a transitional period before getting his approval to use cannabis flowers.
- Currently I am involved in a court case and was asked by a judge to write an expert opinion on a patient, who suffers from ADHD and severe acne inversa. This 44-year old man grew his own cannabis and needed about 4-5 grams a day.

What is important for a doctor?

- First, he should know the legal situation of his country.
- Second, he should know something about the therapeutic potential of cannabis, side effects and dosing.
- In addition, three other issues are of major importance.

First, he should listen to his patients.

Second, he should listen to his patients.

Third, he should listen to his patients.

Thank you very much
for your attention!