Schweizer Arbeitsgruppe für Cannabinoide in der Medizin, SACM
Swiss Task Force for Cannabinoids in Medicine, STCM

Cannabinoide in der Medizin – Eine Option?

Cannabinoids in Medicine – An Option?

Dienstag 22. Januar 2013, 9:15 – 17:30 h
Tuesday 22. January 2013, 9:15 am – 5:30 pm

Universität Bern
Langhans Auditorium Pathologie, Inselspital

University of Bern
Langhans Auditorium Pathology, University Hospital

SAPhS Swiss Academy of Pharmaceutical Sciences

SSPhS Swiss Society of Pharmaceutical Sciences

Einleitung, Ziel der Tagung
Introduction, Intention of the Conference

Die interdisziplinäre „Schweizer Arbeitsgruppe für Cannabinoide in der Medizin (SACM)“ wurde im Jahre 2009 gegründet. Mitglieder dieser Interessensgemeinschaft sind Kliniker, Pharmazeuten, Juristen und andere Personen, die in ihrer beruflichen Praxis - sei es im Sprechzimmer, universitären Forschungslabor, in der Apotheke oder Anwaltskanzlei - mit der Problematik des betäubungsmittelrechtlich ungenügend geregelten medizinischen Einsatzes von Cannabinoiden konfrontiert sind.

Die Schweiz verfolgt eine fortschrittliche Drogenpolitik und spielt, so im Falle der Entwicklung des 4-Säulen-Modells, der Schadensverminderung und heroingestützten Behandlung, eine internationale Pionierrolle. Dies gilt nicht für die Legalisierung des Medizinalcannabis, wo Länder wie Kanada, USA, Holland, Deutschland und Österreich patientengerechte und praktikable Verschreibungsmodelle etabliert haben. Obwohl zahlreiche wissenschaftliche Studien den therapeutischen Nutzen von Cannabinoiden und Cannabis bewiesen haben, ist es leider heute eine Tatsache, dass in der Schweiz gewisse Patienten immer noch gezwungen sind, unkontrollierte Selbstmedikation mit qualitativ nicht abgesichertem Strassenhanf zu betreiben und allenfalls kriminalisiert werden.

Die Tagung der SACM hat deshalb zum Ziel, aktuelle wissenschaftliche, gesundheitspolitische, rechtliche und regulatorische Fakten zu präsentieren, dies als Basis für eine möglichst sachliche Diskussion Pro und Contra Remedizinalisierung der Cannabinoide und Cannabisprodukte. Die Tagung richtet sich an Medizinalpersonen, Wissenschafter, Pflegepersonal, Patienten, Patientenorganisationen, Politiker, Behördenmitglieder und Medienvertreter.

The interdisciplinary „Swiss Task Force for Cannabinoids in Medicine“ (STCM) was founded in 2009. Members of the STCM are clinicians, pharmacists, lawyers and other professionals, who are – either in the doctor‘s office, university research lab, public pharmacy or law office - confronted with the problems of the insufficiently regulated medical use of cannabinoids.

Switzerland pursues a progressive drug policy and plays an international pioneering role, such as regarding the 4-pillar-model, harm reduction and heroin-assisted treatment. This does not apply to the legalisation of medicinal cannabis, where countries as Canada, USA, Netherlands, Germany and Austria have established patient-friendly and practicable dispensation models. Numerous scientific studies have shown the therapeutic benefits of cannabinoids and cannabis. However, it is unfortunately a fact, that in Switzerland some patients are still forced to uncontrolled self-medication by using qualitatively not defined illegal street cannabis, therefore eventually being criminalised.

Consequently, the STCM conference aims at presenting current scientific, health political, legal and regulatory facts as base for an objective pro and cons discussion of the remedicinalisation of cannabinoids and Cannabis products. The conference addresses to medical professionals, scientists, caregivers, patients, patient organisations, politicians, regulatory authorities, and media people.

Tagungsprogramm
Conference Program

08:45 – 09:15 h	**Registrierung , Kaffee** **Registration, Coffee**
09:15 – 09:30 h	**Begrüssung , Einführung** **Welcome Addresses, Introduction**
	Prof. Dr. pharm. Rudolf Brenneisen Universität Bern / SACM PD Dr. med. Barbara Broers Universität Genf / SACM Dr. phil. Lukas Boesch Universität Zürich / SACM
09:30 – 10:50 h	**Session I:** **Pharmazeutische Optionen, Medizinische Einsatzbereiche I** **Pharmaceutical Options, Areas of Medical Use I** Moderation: PD Dr. med. Rudolf Stohler Universität Zürich / SACM
09:30 – 09:50 h	**Endocannabinoidsystem, Cannabinoid-Medikamente** **Endocannabinoid System, Cannabinoid Drugs** Prof. Dr. pharm. Rudolf Brenneisen Universität Bern / SACM
09:50 – 10:10 h	**Anwendungsmethoden – Eine Umfrage** **Methods of Intake – A Survey** Dr. phil. Arno Hazekamp University of Leiden, Netherlands
10:10 – 10:30 h	**Neurologische Erkrankungen** **Neurological Diseases** Dr. med. Claude Vaney Berner Klinik Montana / SACM
10:30 – 10:50 h	**Krebserkrankungen** **Cancer** Dr. Cristina Sánchez Complutense University Madrid, Spain
10:50 – 11:20 h	**Pause** **Break**

11:20 – 12:20 h	**Session II:** **Medizinische Anwendungsbereiche II** **Areas of Medical Use II** Moderation: Dr. med. Claude Vaney Berner Klinik Montana / SACM
11:20 – 11:40 h	**ALS** Bea Goldman Muskelklinik/ALS-Zentrum St. Gallen
11:40 – 12:00 h	**Schmerz, Asthma, Aids, Glaukom** **Pain, Asthma, Aids, Glaucoma** PD Dr. med. Barbara Broers Universität Genf / SACM
12:00 – 12:20 h	**Psychiatrische Erkrankungen** **Psychiatric Diseases** Dr. med. Robert Hämmig Universitäre Psychiatrische Dienste Bern / SACM
12:20 – 13:20 h	**Lunch**
13:20 – 14:40 h	**Session III:** **Rechtliche und politische Situation** **Legal and Political Situation** Moderation: Dr. phil. Lukas Boesch Universität Zürich / SACM
13:20 – 13:40 h	**Schweizer Betäubungsmittelgesetz** **Swiss Narcotic Law** Markus Jann Bundesamt für Gesundheit Bern
13:40 – 14:00 h	**Der Weg zum Cannabis-Medikament** **The Way to the Cannabis Medication** Heidi Tschümperlin Swissmedic Bern
14:00 – 14:20 h	**Position der EKDF** **Position of the EKDF** Dr. med. Toni Berthel Eidg. Kommission für Drogenfragen EKDF
14:20 – 14:40 h	**Position des Bundesparlamentes** **Position of the Swiss Parliament** Prof. Dr. med. Felix Gutzwiller Ständerätliche Kommission für soz. Sicherheit und Gesundheit SGK
14:40 – 15:00 h	**Pause / Break**

15:00 – 16:20 h	**Session IV:** **Verschreibungsmodelle** **Dispensation Models** Moderation: Dr. med. Robert Hämmig Universitäre Psychiatrische Dienste Bern / SACM
15:00 – 15:15 h	**Modell Holland** **Model Netherlands** Dr. phil. Arno Hazekamp University of Leiden, Netherlands
15:15 – 15:30 h	**Modell Deutschland** **Model Germany** Holger Rönitz THC Pharm Frankfurt, Deutschland
15:30 – 15:45 h	**Modell Österreich** **Model Austria** Dr. med. Eberhard Pirich Bionorica Ethics Austria
15:45 – 16:05 h	**Modell Kanada und USA** **Model Canada and USA** Prof. Dr. med. Mark Ware McGill University Montreal, Canada
16:05 – 16:20 h	**Modell Schweiz** **Model Switzerland** Dr. pharm. Manfred Fankhauser Bahnhof-Apotheke Langnau / SACM
16:20 – 16:40 h	**Pause / Break**
16:40 – 17:30 h	**Session V:** **Diskussionsrunde, Schlussfolgerungen** **Roundtable, Conclusions** Moderation: Dr. iur. Andrea Demarmels, SACM
16:40 – 17:20 h	**Fragen, Diskussion** **Questions, Discussion** Alle Referenten All Speakers
17:20 – 17:30 h	**Schlusswort** **Closing Remarks** PD Dr. med. Barbara Broers Prof. Dr. pharm. R. Brenneisen
17:30 h	**Ende der Tagung** **End of Conference**

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Schweizerischer Nationalfonds

Storz & Bickel GmbH Tuttlingen

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1975 Federal Diploma for Pharmaceutical Sciences, University of Bern (UB; 1979 Ph.D. for Phytochemistry & Pharmacognosy, UB;1981-1995 Head Dept. of Phytochemistry & Pharmacognosy, Institute of Pharmacy, UB; 1988 Habilitation (PD) at the Faculty of Medicine, UB; 1985-1995 Consultant/Expert, United Nations International Drug Control Programme (UNDCP); 1993 Associated Professor, UB;1993- Member of the Swiss Guidelines Committee for Drugs of Abuse Testing (SCDAT); 1997- Head Laboratory for Phytopharmacology, Bioanalytics & Pharmacokinetics, Dept. Clinical Research, UB; 2007- Member of the board of directors International Association for Cannabinoid Medicines (IACM); 2008- President Swiss Academy of Pharmaceutical Sciences (SAPhS); Member of the Advisory Board of the Swiss ALS Association.

„Endocannabinoid System (ECS), Cannabinoid Drugs“

Two cannabinoid receptors (CB_1, CB_2), detected in 1988 and 1993, are mainly present in the mammalian brain and immune system, respectively, but also found in heart, bone, skin, eye, liver, gastrointestinal tract, and reproduction organs. CB_1 is a G protein-coupled transmembrane receptor. Several endogenous ligands were identified, such as the arachidonic acid derivatives anandamide and 2-AG. The phytocannabinoid THC binds to both receptors. The ECS is a physiological keyplayer, linked to most neurotransmitter systems and modulating fundamental intercellular communication. It is involved in memory processing, modulation of anxiety, preception of pain, control of movement, sleep, food intake, appetite, etc. Thus, the ECS is essential to life and it relates messages that affect how we relax, eat, sleep, forget and protect. The ECS is a most interesting pharmacological target with natural or synthetic agonists, antagonists as well as inhibitors of ligand transport and metabolism beeing promising therapeutic tools.

Mono-component, in form of natural (phytocannanbinoids, e.g. THC) and (semi-)synthetic cannabinoids, or multi-component preparations, in form of Cannabis or extracts, are options to modulate the ECS. Cannabis-based medicines, so far predominantly used in folk medicine for uncontrolled self-treatment, are Cannabis tea, cigarettes, oils, and cookies. Usually, their quality is undefined, dosage unknown and therefore effects unpredictable. In addition, application modes are harmful or inefficient. Approved, commercially available cannabinoid-based medicines (dronabinol, nabilone, cannabidiol; pills, capsules) and cannabis-based medicines (standardized extracts; sprays) are part of the academic medicine and are prescribed and administered as established, validated galenic formulations, preparations following a „formula magistralis“ (drops, tincture). The pharmacokinetic properties vary depending on the preparation and administration route. The oral bioavailability is low (5-20 %), due to extensive liver first-pass metabolism, and the onset of action slow. Excellent bioavailabilities show oromucosal sprays and pulmonal aerosols, with effects occurring slowly to rapidly. Non-pyrolytic inhalation by using vaporizers, nowadays also available as pocket-size devices, is an efficient, harmless application mode allowing the patient to titrate the dose. The pyrolytic inhalation by smoking Cannabis cigarettes is harmful and, at least in case of a medicinally controlled treat-ment, not recommended. Cannabinoid-based injection solutions are ideal for performing clinical studies. Patients, who decided for whatever reason, to treat themself uncontrolled and without prescribed cannabinoid-based medicines should also have access to quality-certified Medicinal Cannabis, use validated home recipes and apply harmless application forms. Even if not yet compatible with the narcotic law, their criminalization is ethically not acceptable. However, the primary goal must be to approve and market cannabinoid- and Cannabis-based medicines as soon as possible and to develop new application forms (such as skin patches and sublingual tablets). The increasing demand for Medicinal Cannabis requires licensed producers and suppliers. Cannabis Pharmacopoeia monographs could be an option in the context of patient-individualized medicines prepared by the pharmacist.

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Dr. Arno Hazekamp was born on 15 March 1976 in the Netherlands. He studied Molecular Biology at Leiden University, the Netherlands, where he started his PhD in the Phytochemistry department in 2001. His research project was focused on the medicinal properties of the Cannabis plant, and its development into a modern medicine. Arno was able to work closely with the official grower of medicinal Cannabis in the Netherlands, Bedrocan BV, and was part of numerous projects regarding the chemical analysis, quality control, and product development regarding medicinal Cannabis. He was actively involved in setting up the medicinal Cannabis program of the Dutch Health Ministry, and was a strong advocate of a more science-based approach on the medicinal use of Cannabis in the Netherlands and abroad. During his PhD, Arno spent several periods at the Institut Universitaire de Médecine Légale (IUML) in Lausanne, Switzerland, focusing on the forensic aspects of Cannabis use. In the last phase of his PhD study, in 2005, Arno started a phytochemical (plant chemistry) contract laboratory, as a spin-off from Leiden University. Based on the experiences during his PhD work, in the period 2005-2010 he further specialized as a medical Cannabis expert, working closely with government agencies, universities and pharmaceutical companies. Some relevant experiences during this period include: production of GMP-approved Cannabis products for clinical trials; isolation of pure cannabinoid standards for analytical studies on Cannabis products; validation studies for the German company Storz & Bickel, which were the basis for the successful development of the Volcano® Medic, a vaporizer device specifically designed for inhalation of medicinal Cannabis; and setting up the Dutch non-profit organization NCSM to provide science-based information about medicinal Cannabis to the general public. Arno continues to have a strong interest in the medicinal use of Cannabis, with a specific focus on controlled growing, quality control, and safe access for patients. In 2009, he became a board member of the International Association for Cannabinoid Medicines (IACM). In 2011, Arno became the Head of Research and Development (R&D) of Bedrocan BV, where he currently works on the preparation of clinical trials with medicinal Cannabis.

„Methods of Intake – A Survey“

Medicines based on Cannabis or cannabinoids are becoming more popular, but only limited information is available on advantages and disadvantages of different methods of intake (oral, oromucosal, inhalation). Few clinical studies have directly compared the effects of these medicines on patients. Therefore, a questionnaire was designed to determine how patients perceive possible advantages and disadvantages of different methods of intake and which methods or products they prefer over others. The study also intended to analyze whether perceived advantages and preferences depend on demographic parameters (gender, age and country), previous experience with recreational Cannabis use, disease and/or symptoms, or involvement of a physician in the use of cannabinoids.

A cross-sectional survey was conducted by putting a questionnaire on the website of the IACM (International Association for Cannabinoid Medicines, www.cannabis-med.org) between August 18, 2009 and January 31, 2010. It was available in five languages (German, English, Spanish, French, Dutch). The collected information included demographics, diseases and symptoms, medical treatment, Cannabis use pattern, dose, onset of effects and methods of former and current intake of Cannabis or cannabinoids. Participants were asked on advantages of different methods of intake, including onset of effects, ease of dose finding, side-effects, amount of Cannabis needed, etc. The IACM survey provides the largest database of information so far on patients' preferences with regard to the medical use of cannabinoids.

Claude Vaney
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1972-1978 Medical Studies in Bern and Glasgow; 1978 Federal Diploma in Medicine; residency in Neurology in Lausanne, Bern and Vancouver; since 1990 medical director of the Neurological Rehabilitation and MS Centre in Crans-Montana, Switzerland; 2000- 2006 president of RIMS (Rehabilitation in Multiple Sclerosis); former teacher in clinical neurology at the Faculty of Medicine, University of Bern; member of the scientific board of the Swiss MS Society; member of the advisory board of the Swiss ALS Association; member of the International Association for Cannabinoid Medicines (IACM).

“Neurological Diseases”

The therapeutic value of Cannabis for treating neurological disorders has been known to Western medicine for nearly two centuries. The plant was introduced into European medicine from India in 1842 by William B. O'Shaughnessy to relieve pain, muscle spasms, convulsions of tetanus, rheumatism and epilepsy and was used medicinally as Tinctura Cannabis well into the 20th century. Until the invention of aspirin it was used as the primary pain reliever. In 1890 Dr. J. Russell Reynolds, physician of Queen Victoria, noted in an article in “The Lancet” that for "organic disease of a gross character in the nervous centres India hemp (Cannabis) is the most useful agent with which I am acquainted." But because of quality control issues and political pressure in a world of growing drug abuse, Cannabis was eliminated from most modern Western pharmacopoeia in 1961 when the United Nations Single Convention on Narcotic Drugs declared that Cannabis had no medical or scientific benefit. No wonder, as nobody knew at that time that the human body has its own endocannabinoid system with analgesic properties! The discovery of an endogenous cannabinoid system with specific receptors and ligands has led to the progression of our understanding of the actions of Cannabis. It now appears that the endocannabinoid system is complexly involved in basic human physiology, such as in the control of movement, pain, memory and appetite. The detection of cannabinoid receptors abundant in the brain and peripheral tissues suggests that the endocannabinoid system represents a network in the nervous system. High receptor concentrations have been found in the cerebellum, basal ganglia and hippocampus, which are responsible for motor tone, coordination and mood state. Low concentrations are found in the brainstem, explaining the remarkably low toxicity of THC, as lethal doses in humans have not been described. THC, the major psychoactive constituent of Cannabis sativa, and endogenous cannabinoid ligands, such as anandamide, signal through G-protein-coupled cannabinoid receptors localized in regions of the brain associated with important neurological processes. Signalling is mostly inhibitory and suggests a role for cannabinoids as therapeutic agents in CNS diseases where inhibition of neurotransmitter release would be beneficial. Recently, several RCTs showing a positive effect on spasticity might explain why up to 15 % of patients with multiple sclerosis (MS) use Cannabis to relieve disease-related symptoms. Animal models of mechanical, thermal and noxious pain suggest that cannabinoids may be effective analgesics. Indeed, in clinical trials of postoperative and cancer pain and pain associated with spinal cord injury, cannabinoids have proven to be more effective than placebo but may be less effective than existing therapies. Cannabinoids induce proliferation, growth inhibition or apoptosis in a number of cells, including neurons, lymphocytes and various transformed neural and non-neural cells. In the CNS, most of the experimental evidence indicates that cannabinoids may protect neurons from toxic insults such as glutamatergic overstimulation, ischemia and oxidative damage. The neuroprotective effect of cannabinoids may have potential clinical relevance for the treatment of neurodegenerative disorders such as amyotrophic lateral sclerosis (ALS), MS, cerebrovascular ischemia, and stroke. Cannabinoids could be useful in Parkinson's disease by inhibiting the excitotoxic neurotransmitter glutamate and counteracting oxidative damage to dopaminergic neurons. Finally, controlled clinical research with THC on Tourette patients showed positive results without serious adverse effects.

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Cristina Sánchez (Madrid, Spain, 1971) graduated in Biology at Madrid Complutense University in 1994. She started her scientific career as an undergraduate student at the laboratory of Dr. Ramos and Dr. Fernández-Ruiz (School of Medicine, Complutense University), where she first took contact with the field of cannabinoid research. Once graduated, she moved to Dr. Guzmán's laboratory (School of Biology, Complutense University), where she studied the effect of cannabinoids on lipid and carbohydrate intermediate metabolism first and on cancer cell proliferation later. She obtained her PhD with Honors in Biochemistry and Molecular Biology at Complutense University in 2000. During her postdoc at Dr. Piomelli's laboratory (University of California Irvine, 2000-2003) she studied the involvement of another group of bioactive lipids (lysophosphatidic acid and related compounds) on pain initiation. In 2004, Cristina returned to Spain with a "Ramón y Cajal" contract (aimed at repatriating Spanish researchers from abroad) and she started coordinating a new line of research within Dr. Guzmán's laboratory. In particular, the goal of her research is to understand and exploit cannabinoids as potential antitumoral agents in breast cancer. More recently, she has also focused her attention on new cannabinoid receptors and their possible involvement in cannabinoid antitumoral action in breast cancer and other type of tumors. She's currently Associate Professor of Biochemistry at Complutense University Madrid.

„Cancer"

There is compelling evidence indicating that cancer is one of the pathologies that may obtain clinical benefit from Cannabis-related compounds. First, it is well known that cannabinoids have palliative effects in cancer patients. In particular, they inhibit chemotherapy-induced nausea and vomiting, they inhibit cancer-associated pain and they stimulate appetite and attenuate wasting. But the therapeutic potential of cannabinoids in oncology might not be restricted to their aforementioned palliative actions. Thus, numerous studies carried out during the past few years have provided evidence showing that THC and other cannabinoids induce the death of cancer cells in culture and reduce tumor growth and progression on a wide range of animal models of cancer. The mechanisms of anti-tumor action include the induction of cancer cell death, an effect that is not produced in non-cancer cells, the inhibition of angiogenesis and the blockade of invasion and metastasis. At this point, combined efforts from basic researchers, clinicians and pharmaceutical companies should be made to determine whether this knowledge should be transferred from the labs to the clinics.

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Registered nurse, 15 years Intensive Care Unit; since 2003 nurse specialist, study nurse and coordinator at the Muskelzentrum/ALS Clinic St.Gallen; ALS supervisor/teaching for care homes, district nurse services; teacher at the Fachhochschule St.Gallen in neuropalliation and home councelling; leader of Cannabis-self medication programme and ALS care training programme; MSc cand. University of Cardiff, currently writing thesis “Hope in ALS“.

„ALS“

Sativa-Oil Project in ALS Care.

Introduction: ALS is a neurodegenerative, incurable disease of unknown origin and genesis, leading to progressive physical impairment and helplessness. Death results mainly peacefully from respiratory failure. Survival from onset is about 2-4 years. Incidence is 2/100’000, prevalence 6-7/100’000. 5-10 % of patients are still alive after 10 years. In Switzerland, there are estimated 400-800 ALS patients. The standard therapy consists of a disease-slowing drug (riluzole), symptom management and maintenance of quality of life. Apart from the immense non-physical suffering, symptoms such as cramps, spasticity, hypersalivation, pseudo-bulbar symptoms and sleep problems can worsen patients’ quality of life. The increased suffering can also extend to caregivers. Often, medications to treat spasticity and cramps can be insufficient or accompanied by too many side-effects, impairing patients’ quality of life even more.

A*im*: To enable ALS patients to treat themselves with Cannabis of defined THC content in a safe and easy way, under controlled conditions, and at an affordable price.

Method: The nurse introduces a patient-education scheme, consisting of teaching of medical use of Cannabis, use of a symptom diary, FAQ and ongoing support in self-medication in cooperation with patients’ general practitioner/neurologist. The basis of the project was a coincidental finding of an easy-to-use, safe and subsequently validated procedure of a potent Cannabis oil, the so called Sativa-Oil, that could be prepared at home.

Implications for the future: Despite structural and methodological limitations, experiences from the Sativa-Oil Project showed that Cannabis can have a beneficial effect on many ALS symptoms and a positive influence on the well-being and coping of terminally ill patients. The potential benefit compared to the relatively minimal toxicity risk, the high cooperation readiness of involved persons and a very high cost-effectiveness, justifies the implementation of such a project. The prerequisite would be the legal access to medical Cannabis and structures for patients, which are the biggest problems at present. To date this is the first systematic, European patient self-medication programme using Cannabis. The programme could be beneficial to many other groups of patients, too.

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Barbara Broers, MD, MSc, PD. Head of the Unit for Dependencies, Department for Community Health, Primary Care and Emergencies of the Geneva University Hospitals; senior lecturer at the Faculty of Medicine, University of Geneva; vice-president of the Federal Commission for Drug-Related Affairs, and the Swiss Society for Addiction Medicine (SSAM); over 20 years of clinical experience in the field of HIV, hepatitis and addiction.

„Pain, Asthma, Aids, Glaucoma“

Although most clinical research on the use of cannabinoids in medicine concern the field of neurology and oncology, the therapeutic benefits of Cannabis and cannabinoids have been documented in different other domains. This presentation discusses four domains. Still, formal randomized clinical trials lack for most of these domains, so in general it is not possible to provide practical guidelines for prescription.

Pain: Both basic research, animal and human studies suggest analgesia is an important physiological function of the endocannabinoid system, and of clinical relevance. Endocannabinoids and exocannabinoids seem to act as analgesics in models of both acute nociception (mediated through CB1) and clinical pain such as inflammation (mediated through CB2) and painful neuropathy. Clinical studies show that Dronabinol prescribed for pain in elderly is not always well tolerated.

Asthma: The potential benefit of cannabinoids on asthma can be explained by two mechanisms. First, the activation of CB2 receptors on mast cells has direct anti-inflammatory effects, causing decreased release of pro-inflammatory mediators by these cells. Second, the activation of CB1 receptors on bronchial nerve endings has bronchodilator effects by acting on the airway smooth muscle and may be beneficial in airway hyperreactivity and asthma.

AIDS: Different medications that activate cannabinoid receptor pathways have been tested, and are approved as treatments for cachexia, nausea (medication-related or not) or neuropathic pain in HIV/Aids patients. Positive impact on HIV-related disease can occur via improved adherence to antiviral treatment. Definite clinical studies on the impact of cannabinoids on the progression of HIV-related immunity and disease progression are lacking. Still, different laboratory studies show an attenuated progression of HIV (or Simian Immunodeficiency Virus) after cannabinoids administration. Another recent study suggests that this beneficial adjunctive antiviral effect against CD4-tropic viruses (in late stages of HIV-1 infection) is mediated through CB2 activation.

Glaucoma: Increased intraocular pressure (IOP) is the primary risk factor for glaucoma, a cause of blindness. Cannabinoid agonists are known to decrease IOP, probably through actions at CB1 receptors within the eye, and through adrenergic receptors. Different topical applications are under study.

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Schools in Zurich, Bolligen and Bern, 1971 matura type B (Latin and English); studies in medicine, University of Bern; 1978 graduation in human medicine; 1979-1980 Kantonale Psychiatrische Klinik Beverin, Cazis (1 year); 1980-1982 Psychiatric University Clinic PUK Bern (3 years); 1983-1984 Geriatrics/Rehabilitation, Zieglerspital Bern (1 year); 1984-1987 Social Psychiatry University Clinic Bern (SPUK)/Stiftung Contact Bern (3 years); 1987- Managing director of Integrated Drug Service, University Psychiatric Services Bern; since 2006 director of Addiction Department, member of directorial board of the University Psychiatric Services Bern; 2000-2008 studies in Cultural Anthropology, University of Bern.
Medical managing tasks: Addiction department of Psychiatric University Hospital Bern (alcohol & drugs); KODA-1 & 2 Bern (Heroin-Assisted Treatment); Zentrum für ambulante Suchtbehandlung ZAS Bern (methadone and buprenorphine-assisted treatment); relapse prevention (using naltrexone and group therapy), outpatient detox (with buprenorphine), and buprenorphine-assisted treatment CleaNex; medical consultancy in the safe injecting facility Hodlerstrasse Bern; lecturer at the University of Bern for “Psychology and Psychiatry for Dentists”; research group for drug addiction.
Member of: National Research Mandatary for Swiss Multicenter Detoxification Studies; Federal Expert Committee for Aids (1985-2000); Swiss Society for Addiction Medicine SSAM (president); International Society for Addiction Medicine ISAM; Suchtmittel- und Gesundheitsförderungs-kommission des Kantons Bern (expert committee for addiction and health promotion of the Canton of Bern); Fachverband Sucht (Swiss society of experts in addiction); Swiss Medical Society for Psycholytic Therapy; Harm Reduction International (HRI); expert group for harm reduction of the Swiss Federal Office of Public Health; Swiss Society for Psychiatry and Psychotherapiy SGPP; Bernese Society for Psychiatry and Psychotherapy BGPP.

„Psychiatric Diseases“
In recent years the debate on cannabinoids in psychiatry was dominated by the question whether Cannabis causes schizophrenia. However, beyond this mainly political question research on this topic yielded some interesting insights in the mechanism of schizophrenia and the functioning of the central nervous endocannabinoid system as well. Of special interest is the non-psychotometic cannabidiol (CBD), one of the many plant-derived cannabinoids, as it modulates and partly counteracts the effects of THC. In addition to a possible anti-psychotic effect CBD seems to have anxiolytic and anti-depressive effects. This is important as the burden of disease from anxiety disorders and depression is high. These effects are corroborated by a large body of animal studies, but only a few human trials. It is discussed that all psychiatric disorders could stem from a misbalance of the endocannabinoid system, thus a therapeutic strategy could be to restore this balance. Considering the severe adverse effects of the antagonist/inverse agonist rimonabant (a drug withdrawn from the Swiss market) research seeks instead of only directly also indirectly influencing the system (metabolism, membrane transport).

Markus Jann
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Markus Jann studied psychology and journalism at the University of Freiburg. He began his professional career in Bern in the world's first injection room for drug addicts (1985). He then spent three years as a research associate with "Sucht Schweiz" (Swiss Addiction) and four years as an Addiction counsellor and Head of the scientific service of the Foundation Contact-Netz Bern. He was then appointed by the Canton of Bern as the delegate for addiction questions and health promotion. He has been Head of the drug section in the Federal Office of Public Health for the past eleven years and in this position is responsible for the "Four Pillar Drug Policy" of Switzerland and for questions regarding children's and young people's health.

„Swiss Narcotic Law"

The Swiss Federal Law on Narcotic Drugs and Psychotropic Substances (Federal Law on narcotic drugs, BetmG, 812.121) is intended to regulate the licit availability of narcotic drugs for medical and scientific purposes, to prevent illicit consumption of narcotic drugs, to reduce the harm related to the abuse of illicit drugs for the individual as well as for the public as a whole and to combat crime related to illicit drugs. Article 8 of the BetmG deals with internationally controlled narcotic drugs such as opium, diacetylmorphine, hallucinogens or substances of the Cannabis type. Generally, these narcotic drugs may neither be produced, manufactured, exported, imported, distributed, traded in, used or possessed without appropriate authorizations by the competent federal and cantonal authorities.

The Federal Office of Public Health (FOPH) can grant exceptional authorizations for scientific research, the development of medicinal products or for limited medical use (compassionate use) of narcotic drugs. Pursuant to the Federal Law on Medicinal Products and Medical Devices (Art. 9 par. 4, Therapeutic Products Act, HMG, 812.21), unauthorized medicinal products can be authorized for a limited period for life-threatening diseases in order to support health, as long as a major therapeutic benefit can be expected from such use and if no comparable medicine is available.

So, in line with this legal situation, substances of the Cannabis type can be made available for limited medical use. Where an authorized medical product based on Cannabis is available, it can be prescribed, without any additional authorizations, in analogy to other medicines containing controlled substances (a special control regime has been put in place for the medical use of diacetylmorphine, heroin).

Pursuant to Article 19 BetmG and to the report of the Federal Commission for Social Security and Health, issued by the National Council on 4th May 2006 on the Parliamentary Initiative Partial Revision of the Federal Law on Narcotic Drugs, the cultivation of Cannabis for personal use as well as the consumption for self-medication continue to be prohibited. In minor cases and for insignificant quantities, the degree of penalty can be reduced or suspended.

To obtain an exemption authorization for the limited medical use, a complete application has to be submitted to the FOPH with details on the patient, on the indication and on the dispensation (see the FOPH factsheet http://www.bag.admin.ch/themen/drogen/00042/02942/02948/index.html?lang=de). Up to now some 150 exemption authorizations for the limited medical use of narcotic drugs of the Cannabis type have been issued during the last six-month period. One request concerning a Cannabis substitution therapy had to be refused.

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The Way to the Cannabis Medication

Neither Dronabinol ([-]-trans-Δ^9-THC) nor Cannabis extracts have been included to date in any synthetic or herbal medicinal product that is or has been authorized by Swissmedic. With the enactment of the ordinance on the control of narcotics of May 25th 2011 the application for marketing authorization for a medicinal product containing preparations made of Cannabis is possible since July 1st 2011 (commencement date).

Any person applying for a marketing authorization for a medicinal product must have a registered address, registered office or a branch office in Switzerland; be a holder of an authorization to manufacture, import or conduct wholesale trade issued by the competent authority; prove that the medicinal product is of high quality and is safe and effective (documentation according to the Ordinance on the Authorization of Medicinal Products (AMZV) Art. 3-6). In case of a product containing preparations made of Cannabis an establishment license for narcotics is necessary prior to the application for authorization.

In case of an application for authorization of a synthetic medicinal product containing Dronabinol as active substance, the examination of the documentation would take place according to the *Instructions for the authorization of human medicines with new active pharmaceutical ingredients (New API) and major variations*.

In case of an application for authorization concerning a herbal medicinal product with a preparation made of Cannabis as active substance, the evaluation of the documentation would take place according to the *Instructions for the submission of authorization applications for herbal medicines for human use (Instructions for herbal medicines)*.

For herbal medicinal products, trials on therapeutic efficacy and safety may in certain cases (according to the Ordinance of the Swiss Agency for Therapeutic Products on the simplified Authorization of Complementary and Herbal Medicinal Products (KPAV) Art. 7) be replaced even for new pharmaceutical ingredients by treatment records or bibliographical documentation, as long as the published scientific literature provides sufficient proof and as the results apply analogously to the medicinal product in question. Own clinical trials or new clinical data have to be submitted concerning those aspects, which cannot be proven by scientific literature.

In either case - synthetic or herbal medicinal product - the indication and the supply category would be decided on after the evaluation of the submitted documentation.

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„Position of the EKDF“

For the last decades, the Federal Commission for Drug-Related Affairs (EKDF) as expert panel has actively cooperated in solving the drug problem in Switzerland. The EKDF always supported a comprehensive drug policy not only focusing on drugs. The EKDF argues that substances used unproblematically by most adults should not be banned. This particularly also holds true for substances which - when used indicated, deliberately and controlled - show a curative effect or can alleviate mental or physical distress. The EKDF promotes the use of medical Cannabis in a pragmatic and practical way and within a broad, evidence-based spectrum of indications. The EKDF thinks that it should be evaluated whether or not the Cannabis plant with its numerous constituents can be used for therapeutic purposes. The EKDF is also in favour of further, clinically tested Cannabis-based drugs being reimbursed by health insurances.

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„Position of the Swiss Parliament“
(not available)

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„Model Netherlands“

The number of countries that provide an official source of Cannabis to chronically ill patients is growing. Canada (since 2001) and The Netherlands (since 2003) have had a government-run program for the last decade, supplying quality-controlled herbal Cannabis grown by specialized companies. Other countries are now following this example, either by setting up their own program (Israel, Czech Republic) or by importing products from The Netherlands (Italy, Finland, Germany, Switzerland).

The medicinal Cannabis program of The Netherlands, supervised by the Office of Medicinal Cannabis (OMC) of the Dutch Health Department, offers pharmaceutical grade Cannabis on prescription to chronically ill patients suffering from multiple sclerosis, cancer, HIV/Aids, chronic pain, therapy-resistant glaucoma, and Tourette’s syndrome. The product is cultivated by the contracted company Bedrocan BV, and dispensed through pharmacies in the form of granulated dried female flowers (Cannabis Flos). Patients are advised to administer medicinal Cannabis by using a Cannabis inhaler or by preparing a tea. In a growing number of cases, costs are reimbursed by health insurance companies.

Because the Dutch program makes standardized Cannabis materials with different compositions of active components available on a large scale, it also provides an opportunity for long-term research projects, clinical trials, as well as development of pharmaceutical products. This presentation will give an overview of the current status and the results of the Dutch program.

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„Model Germany"

From Patient Initiative to providing Dronabinol as a magistral preparation to patients.

The reintroduction of natural cannabinoids in Germany (as well as in Switzerland and Austria) can be traced back to a patient initiative formed by Dr. Christian Steup, Dr. Joachim Hartinger and Holger Rönitz in 1996. Until then, patients suffering from pain, spasticity, loss of appetite, nausea or vomiting were forced to use uncontrolled and illegal Cannabis from the black market. Dr. Hartinger who had sustained a spinal cord injury, leaving him partially paralyzed, was looking for a legal, safe and qualitatively controlled alternative to the Cannabis joints and teas that had had a positive effect on his painful spasms. Above all, he was looking for a medical treatment that would allow him to continue work as a microbiologist researcher in one of Germany's leading research institutes. When it became apparent that the pharmaceutical industry was not interested in the substance class, the patient initiative founded "THC Pharm – The Health Concept" in order to provide cannabinoids to patients meeting this unmet medical need. The activities of the initiative were closely monitored. As a result of an antiquated and hysteric drug policy the premises of THC Pharm were raided several times and the applications for Cannabis extracts were turned down. However, in 1998 the rescheduling of the naturally occurring delta-9-THC (or Dronabinol) provided an opportunity to supply patients with cannabinoids on a controlled substance receipt. Because THC Pharm was not grated a trading license, the first batches of Dronabinol and the magistral preparations were done in the Bock Apotheke, one of Frankfurt's pharmacies with extensive expertise in formula magistralis preparations. THC Pharm developed and patented the production of Dronabinol from cannabidiol (CBD), which was derived from fibre hemp supplied by local farmers. As of the year 2000, magistral Dronabinol preparations could be done in every pharmacy in Germany. Application forms range from oily drops to capsules or inhalation with a vaporizer. To supplement the natural THC isomer, THC Pharm developed a Cannabis extract which could only be prescribed on a patient-name basis. With the appearance of a second Dronabinol producer and more media attention for indications such as polio and fibromyalgia, health insurers started to handle Dronabinol prescriptions more restrictively.

In 2005, the Federal Institutional Court ruled that Dronabinol had to be reimbursed by health insurers, provided 3 criteria were met: (1) The indication had to be classified as very severe, (2) there were no other therapeutic options available, and (3) there was some (not necessarily phase 3 study supported) scientific evidence about the medical benefit. However, local and regional social security courts did not necessarily follow the ruling until the Federal Social Security Court defined these criteria very narrowly. At present it is estimated that approx. only 35-40 % of the receipts are reimbursed while more and more doctors refuse to prescribe Dronabinol to avoid conflicts with the health insurers. Some patients who do not get Dronabinol have managed to obtain exceptional permissions for using either certified Cannabis flowers or some Cannabis extracts but the procedure is very complex and the numbers are negligible when compared to Dronabinol. Despite some good clinical experiences with the Cannabis extract, the German law does not allow the therapeutic option of Cannabis extracts with the exception of Sativex® which is available since 2011 but can only be prescribed for one very limited indication (painful spasticity in advanced MS) and when everything else has failed. Several parliamentary initiatives have established the benefits of the formula magistralis preparation but the reimbursement issue is still the biggest impediment to the unmet medical need. New studies regarding the use of Dronabinol in paediatric palliative care and specialized in house palliative care are expected and some insurers have indicated their willingness to speed up the decision making progress for the most imminent prescriptions.

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„Model Austria“

Prescription and Reimbursement of Cannabinoids in Austria

Cannabinoids available for prescription in Austria are currently limited to Dronabinol, nabilone and Sativex®; Marinol® is not marketed. Dronabinol can be prescribed as formula magistralis drug (2.5 % solution for drops or capsules of different strengths). Since the very beginning, Bionorica’s main approach is to familiarise physicians with the vital role played by the endocannabinoid system in a growing number of diseases as well as with clinical results and other scientific progresses made with exocannabinoids. For this, relevant information has been made available for physicians that are regularly updated. A couple of publications in national journals have resulted from cases successfully treated with Dronabinol (e.g., from Klinikum Klagenfurt, Likar R: Dronabinol in der Schmerztherapie / Palliativmedizin. Facharzt 2008;1:4-6; Blaas K: Depressionsbehandlung mit Cannabinoiden. Cannabinoids 2008; 3(2):10-13). In parallel, Dronabinol is prescribed in the internationally approved indications, severe nausea and vomiting associated with cancer chemotherapy, as well as Aids-related anorexia associated with weight loss. In 2012, approximately 2.4 kg Dronabinol have been processed as formula magistralis drug (equivalent to about 2,500 to 3,500 patients treated for various conditions). Dronabinol can be reimbursed if prescribed as *“ultima ratio*”. About two thirds of the volume is used in primary care, the rest is used in hospitals. Nabilone is imported as Cesamet® but prescribed as formula magistralis drug. Although not classified as narcotic, it is not reimbursed in primary care because it is too expensive. About 0.12 kg is processed annually. Sativex® (nabiximols) is available on the Austrian market since November 2012 only; data on prescriptions are not yet available. Medicinal Cannabis or “home-grown” Cannabis for personal use is not allowed. The currently sold Dronabinol is prepared semi-synthetically, via cannabidiol (CBD), from industrial (fibre) hemp grown in Lower Austria. The naturally occurring Dronabinol is (-)-THC, which is the most potent isomer. In the near future, extremely pure, natural Dronabinol prepared from Cannabis sativa L. in cooperation with the Austrian Agency for Health and Food Safety (AGES) will become available.

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Dr. Mark A. Ware MBBS MRCP(UK) MSc is Associate Professor in Family Medicine and Anesthesia at McGill Universit Montrealy. He is the Director of Clinical Research of the Alan Edwards Pain Management Unit at the McGill University Health Centre, co-Director of the Quebec Pain Research Network, and Executive Director of the non-profit Canadian Consortium for the Investigation of Cannabinoids. He is a family physicians and practices pain medicine at the Montreal General Hospital and at the primary care pain clinic of the West Island of Montreal. Dr Ware's primary research interests are in evaluating the safety and effectiveness of medicines derived from Cannabis (cannabinoids), population-based studies of the impact of pain on the population, and complementary therapies in pain and symptom management. His research is funded by the FRSQ, CIHR, and the Louise and Alan Edwards Foundation.

„Model Canada and USA"

Since 1999, Canada has evolved a regulatory system of providing Cannabis to patients for medical purposes. Currently over 20,000 Canadians have legal access to Cannabis, and the number is growing exponentially. The regulatory model in Canada has undergone several changes over the past 14 years, and the most recent regulatory framework was released in December 2012 for public consultation and is expected to be finalized later in 2013 and to implemented in 2014. The rationale for the most recent policy revision is to improve public safety and patient access.

This presentation will briefly describe the history of Canadian Medical Cannabis policy, summarize the latest regulatory proposals, and provide a perspective on the potential impact of the new policy on patients and health care providers.

Many countries around the world are in the process of developing Medical Cannabis policy. Currently such development is happening in the absence of true interaction between health professionals, policy makers and patients within and between these jurisdictions. This presentation will conclude with an appeal for international collaboration in the field of Medical Cannabis policy development, and provide some suggestions for how such collaboration may inform, guide and improve local policy initiatives.

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Manfred Fankhauser was born in 1963 in Trub. After his graduation in high school, he studied Pharmacy at the University of Bern and obtained the Diploma as Pharmacist with state examination in 1991. Since then, he has been working in Langnau in the region of Emmental in his own Pharmacy. The dissertation followed in 1996 and was devoted to „Hashish as Remedy“, a topic of pharmaceutical history. Manfred Fankhauser is member of the IACM and also author of many lectures and publications to this topic. Since 2004, he is also lecturer for Pharmaceutical History at the ETH Zurich.

„Model Switzerland“

The use of Cannabis drugs has an old tradition in Switzerland. Before Cannabis was also banned in Switzerland in the 1950s, cannabinoids were well established and accepted medicines. In fact at the beginning of the 20th century, Prof. Bürgi of the University of Bern was conducting major research with cannabinoids and several scientific papers had been published. The therapeutic comeback of Cannabis was almost impossible since the Swiss Narcotics Law was introduced in 1951. Cannabis was therefore only allowed for scientific purposes. At the beginning of the 21th century a form of liberalization again happened, as since then under strict conditions „Marinol®“, THC-containing capsules, can be prescribed for few patients. In 2008 the Swiss Federal Office of Public Health released an exceptional authorization for the first pharmacy, to produce and market the oil drops „Dronabinol“. According to the Law, this was only possible when using fully synthetic THC (Dronabinol). The prescription of these 2,5 % THC formula magistralis drops requires a license and the costs are only partly covered by health insurances. In the last 5 years more than 500 patients have been using this medication, mainly suffering from spasticity due to multiple sclerosis or other neurological diseases. Other indications are tumor pain, chronic pain, neuropathies, amyothrophic lateral sclerosis (ALS), appetite loss, etc.

On July 1, 2011 the revised Swiss Narcotic Law was coming into effect. Consequently, this now allows the medical use of naturally derived cannabinoid preparations, such as THC (isolated from Cannabis) drops or an alcoholic Cannabis tincture. The tincture, which is produced with domestic Cannabis, is standardized on THC and cannabidiol (CBD) at a ratio of 1:2. Currently, only one Pharmacy in Switzerland is allowed to supply this tincture. So far, about 40 patients have received this preparation. However, special permits are required and indications are limited. An advantage of the Cannabis tincture compared to the Dronabinol solution is the price. The costs of such a treatment are about 40 % lower.

The experiences of the last five years have shown, that Cannabis preparations are a valuable therapeutical option for certain patients. Whether or not Cannabis will again be established as drug in Switzerland must show the future.