



International Conference on Medicinal Cannabis

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Reader

2 CONTENTS

2	CONTENTS.....	1
3	AUSTRIA	2
3.1	Legislation and practical solutions.....	2
3.2	Political circumstances.....	2
3.3	Standardisation of the product	2
4	BELGIUM	4
5	CANADA	6
5.1	Political circumstances.....	6
5.2	Pertinent Canadian Legislation	6
5.3	Canadian supply of marijuana.....	8
6	FRANCE.....	9
7	GERMANY	10
8	THE NETHERLANDS.....	13
8.1	Legislation.....	13
8.2	Policy with regard to medicinal use of cannabis.....	14
8.3	Cannabis supply possibilities	14
9	NORWAY.....	17
9.1	Legislation and practical solutions.....	17
9.2	Controlled substances	17
9.3	Drug use and possession	17
9.4	Trafficking and drug related crime	18
9.5	Prosecution and judicial practice	18
9.6	Political circumstances.....	19
10	SWITZERLAND	20
10.1	The Swiss drug policy.....	20
10.2	Status of the political situation.....	20
10.3	The new cannabis policy in Switzerland.....	21
10.4	The medical use of cannabis and its active ingredients	21
11	UNITED KINGDOM	23
11.1	Legislation.....	23
11.2	Studies.....	23
11.2.1	GW Pharmaceuticals (GWP)	23
11.2.2	Cannabis in Multiple Sclerosis (CAMS) Study	24
12	ANNEX I: Relevant articles from the Single Convention on Narcotic Drugs.....	25
13	ANNEX II: Guidelines for cultivating cannabis for medicinal purposes (The Netherlands)	26
14	ANNEX III: Inventory of recent and ongoing trials with cannabis	32

3 AUSTRIA

3.1 Legislation and practical solutions

According to Austrian narcotic drugs legislation, cannabis (hemp) is classed as a “narcotic drug”. It is defined as “inflorescence or fructification of the plants belonging to the genus cannabis whose resin has been extracted”. Exemptions exist for the inflorescence and fructification of some hemp varieties that are used for industrial purposes and whose tetrahydrocannabinol (THC) concentration does not exceed 0.3% (i.e. these do not fall under narcotic drugs legislation).

On principle, medicines containing narcotic drugs may be prescribed, dispensed or applied within the framework of a medical or veterinary therapy only on the basis of the findings and experiences of medical science.

There are, however, some narcotic drugs that must not be prescribed in accordance with applicable regulations in Austria. This explicitly applies to cannabis and cannabis preparations. Likewise, the cultivation of plants for obtaining narcotic drugs is explicitly prohibited in Austria — though there are some exceptions, for example for certain scientific institutes. However, a differentiation needs to be made between cannabis and the agents tetrahydrocannabinol or delta-9-tetrahydrocannabinol (= dronabinol) that are extracted from the plant. Tetrahydrocannabinol is not used in medicine so that the prescription of tetrahydrocannabinol and THC-containing medication is prohibited by the Narcotic Drugs Ordinance (*Suchtgifverordnung*).

The isomer “delta-9-tetrahydrocannabinol”, however, is the agent extracted from cannabis plants or produced synthetically that is used in medicine. It is contained in the drug “Marinol” licensed in the US for the indications of:

- AIDS-related anorexia associated with weight loss,
- nausea and vomitus linked to cancer chemotherapy in patients showing an inadequate response to conventional antiemetic treatment.

This active ingredient may also be prescribed by doctors in Austria.

For the time being, no medical drug containing delta-9-tetrahydrocannabinol as an active ingredient has been approved and no application for approval has been submitted in Austria; upon prescription by a doctor, Marinol as well as nabilone — a THC derivative with a similar action pattern as dronabinol — may be imported by a public pharmacy into Austria .

In addition, there are Austrian doctors prescribing delta-9-tetrahydrocannabinol (dronabinol) in the form of magistral preparations in capsules. This is permitted under Austrian narcotic drugs legislation. In this form, the medicine is less costly for the patients than imported Marinol.

3.2 Political circumstances

Clinical studies are under way for further indications, in particular for multiple sclerosis and pain alleviation, but they have not been completed as yet. Depending on their results, a decision will have to be taken on the issue whether prescription will be permitted for other indications as well.

3.3 Standardisation of the product

In case of plant medicines, such as the agents extracted from cannabis or synthetically produced, the agent’s concentration depends, in particular, on climatic conditions, type of cultivation, soil properties and many other small factors.

The standardisation of a plant product, in this case of tetrahydrocannabinol, mainly offers the advantage of guaranteeing that the patient always receives the same amount of the agent.

According to the international scientific literature available, the prescription of preparations containing delta-9-THC in a standardised concentration is advisable if administered orally for clearly defined indications.

4 BELGIUM

The federal Government presented its drug policy evaluation report to Parliament.

The Council of Ministers of 27 January 2000 decided to establish a working group designed to examine drug problems from a wide perspective.

According to the federal Security and Detention Plan, the working group was required to submit a policy note at the federal level covering:

- An evaluation of the situation
- A round-up of the situation in neighbouring countries
- Recommendations put forward by the federal Government

The federal Government's drug policy note aims at solving the major problems associated with drug consumption and addiction in today's society.

The policy note confirms that drug abuse is a public health problem in the context of a standardization policy focused on rational risk management. The federal Government's policy affects both the supply and the demand side.

The note comprises several action points, divided into five chapters:

- An integrated and comprehensive approach
- Evaluation, epidemiology and research
- Prevention
- Assistance, risk reduction, and rehabilitation and reintegration
- Control

It is preferable to tackle problem drug use (that is not crime-related) by offering assistance focused on reintegration rather than punishing the drug user, thereby even causing more harm. After all, prevention is better than cure. Consequently, the federal Government is in favour of efficient drug prevention.

Instituting criminal proceedings against drug users remains the last resort. It is thought appropriate only when the drug user has committed a crime against law and order. What nature this law enforcement should take depends on the gravity of the offence and on the state of the person involved. (Problem) drug addicts who come into contact with the police or with the law should in the first place be directed towards assistance. Drug use as such should not automatically lead to punitive action, except in some specific high-risk situations such as driving under the influence of illicit drugs.

This is the gist of the Belgian policy on drugs. In fact, the regulations concerning narcotic drugs and psychotropic substances have not fundamentally changed yet.

If we now leave the federal Government's drug policy aside and concentrate on the problem that brought us together in the first place, I would like to emphasize that Belgium, in line with the recommendations of the INCB reports, wanted to initiate clinical trials with medicines containing one or more tetrahydrocannabinols.

These trials should have been conducted for a limited number of indications:

- ◆ Nausea and vomiting during chemotherapy and radiotherapy
- ◆ Glaucoma
- ◆ Multiple sclerosis (spasticity)
- ◆ AIDS-related syndrome
- ◆ Chronic pain when all other pain management therapies have failed

As you can see, the number of indications is very limited indeed. In addition, the opinion of the Ethics Committee is required before any trial can be started.

Following the publication of the Royal Decree, we were faced with the problem of acquiring the active principles without violating the provisions of the international Conventions. We therefore contacted our neighbours to find a practical solution to this problem.

That is why we have come together here today. We do hope that we will be able to open up a new supply line of standardised tetrahydrocannabinol-containing medicines in compliance with the requirements of the international Conventions.

5 CANADA

5.1 Political circumstances

In response to requests from individual patients who requested access to marihuana for medical purposes, Health Canada, in consultation with health professionals and legal advisors, developed a process for exemptions for medical purposes under the authority provided in section 56 of the *Controlled Drugs and Substances Act* (CDSA) (see section below). This exemption allowed an individual, under special circumstances, to possess and/or cultivate marijuana for his/her own purpose. The exemption allowed for a possession of a maximum of 30g at any given time and for the cultivation of a maximum of 7 plants. The first exemption was issued in June 1999.

On July 31, 2000, the Court of Appeal for Ontario rendered its decision in the case of Terrance Parker who used marihuana to help control his epilepsy. The Court dealt exclusively with the issue of medical use of marihuana. The Court upheld a 1997 lower court decision to stay the charges against Mr. Parker on constitutional grounds and raised issues related to the section 56 exemption process of the CDSA, such as the broad discretion given by the law to the Minister of Health to grant exemptions, transparency of the process, and what constitutes medical necessity.

As a result, the Court declared the prohibition of marihuana in the CDSA to be unconstitutional and of no force and effect. The declaration of invalidity was suspended for a year, however, to avoid leaving a gap in the regulatory scheme.

Subsequent to this Court decision, Health Canada announced on September 14, 2000, its intention to develop a new regulatory approach for Canadians to access marihuana.

On July 4, 2001, Health Minister Allan Rock announced that the Government of Canada's regulations governing possession and production of marijuana for medical purposes had been approved. The new Regulations, called *Marihuana Medical Access Regulations* (MMAR) came into effect on July 30, 2001. These Regulations apply only to marihuana.

5.2 Pertinent Canadian Legislation

" *Controlled Drugs and Substances Act* (CDSA)

The *Controlled Drugs and Substances Act* (CDSA) prohibits possession, double doctoring, trafficking, possession for the purpose of trafficking, importation, exportation and possession for the purpose of exporting and production of substances included in schedules to the CDSA. These activities are illegal unless authorized in Regulations made under the CDSA.

One set of these Regulations, the *Narcotic Control Regulations*, regulates the legal distribution of "narcotic" drugs such as opium, codeine, morphine, heroin, cocaine and Cannabis (marihuana).

" *Marihuana Medical Access Regulations* (MMAR)

These Regulations define the circumstances and the manner in which access to marijuana for medical purposes are permitted. They spell out three categories of people who can apply to possess marijuana for medical purposes.

Category 1: This category is for applicants who have terminal illnesses with a prognosis of a life span of less than 12 months. A medical practitioner must provide a medical declaration.

Category 2: This category is for applicants who suffer from specific symptoms associated with certain serious medical conditions, namely:

- " Multiple Sclerosis: severe pain and/or persistent muscle spasms;
- " Spinal Cord Injury: severe pain and/or persistent muscle spasms;
- " Spinal Cord Disease: severe pain and/or persistent muscle spasms;
- " Cancer: severe pain, cachexia, anorexia, weight loss, and/or severe nausea;
- " AIDS/HIV infection: severe pain, cachexia, anorexia, weight loss, and/or severe nausea;
- " Severe forms of Arthritis: severe pain; and
- " Epilepsy: seizures

Applicants must provide a declaration from a medical specialist to support their application.

Category 3: This category is for applicants who have symptoms associated with a serious medical condition, other than those described in Categories 1 and 2, where among other things conventional treatments have failed to relieve symptoms of the medical condition or its treatment. Declarations from two medical specialists must accompany the application.

The declaration from medical practitioners and medical specialists must confirm, among other things, that conventional treatments for symptoms have been tried or considered and were found to be medically inappropriate.

Applicants must provide to Health Canada information about themselves, their medical condition, and indicate if they plan to grow their own supply of marijuana or have someone grow it for them.

Holders of an authorization to possess can obtain marijuana for medical purposes from three possible sources:

- " they can grow their own supply;
- " they can designate someone else (called designated person) to grow it for them;
- " in the future, they should be able to obtain it from Health Canada.

Holders of an authorization to possess may possess a maximum 30-day treatment supply of marijuana at any given time. For example, a patient whose daily dosage is 3 grams will be allowed to possess no more than 90 grams (3 grams x 30 day treatment) at a given time.

A designated person must be 18 years of age or older, and ordinarily a resident of Canada. A designated person is issued a production licence and an identification card. A production licence is required to grow marijuana for medical purposes. A designated person is allowed to hold only one production license (i.e. grow for one person only).

Plants can be grown indoors or outside, providing specific criteria are met. Growers must take the necessary precautions to protect plants and the dried marijuana from loss or theft. The amount of marijuana that can be grown and stored at any time depends on the daily dosage that has been prescribed by a physician, and whether plants are grown indoors or outside.

" ***Food and Drugs Act and Regulations***

Drugs are approved for sale in Canada under the *Food and Drugs Act and Regulations (F&DR)*. The F&DR provide controls respecting the safety, efficacy and quality of products offered for sale in Canada as well as the importation, distribution and sale of approved drugs.

Marihuana has not been reviewed for safety or effectiveness and has therefore not been approved for sale as a drug in Canada. Most scientific experts assert that marihuana's future as a drug lies primarily in its pharmacologically active components, the cannabinoids.

Within the full set of approved pharmaceutical treatments available to patients, there are two commercially available drugs related to marihuana: MARINOL[®], which contains chemically synthesized THC; and CESAMET[®], a synthetic cannabinoid. In Canada, both drugs are approved for

the treatment or management of severe nausea and vomiting associated with cancer chemotherapy and may be prescribed by physicians. MARINOL[®] has also been approved for the treatment of anorexia associated with weight loss in patients with AIDS.

5.3 Canadian supply of marijuana

Prairie Plant Systems Inc. (PPS) of Saskatoon, Saskatchewan was selected through a competitive process in December 2000 to provide Health Canada with a reliable source of affordable, quality, standardized marijuana to meet medical and research needs in Canada.

Under the terms of the five-year, \$5.7 million contract PPS signed with Health Canada, the company will:

- " set up and operate a marijuana growing, processing, fabrication and storage establishment;
- " conduct laboratory testing and quality control of marijuana throughout the product life cycle;
- " fabricate, package, label and store marijuana material;
- " distribute marijuana product to recipients authorized by Health Canada; and,
- " conform with the requirements of the CDSA including stringent security and physical measures.

Marijuana produced domestically will be used for research to gather scientific information on the safety and efficacy of the drug in alleviating patients' symptoms which are unresponsive to currently available treatments. It will also be made available to authorized Canadians using it for medical purposes who agree to provide information to Health Canada for monitoring and research purposes.

The contract provided for an initial six month period to permit the contractor to construct the necessary premises and to obtain the necessary permits. In July, 2001 officials from Health Canada conducted an inspection of the premises located in the unused portion of a mine in Flin Flon, Manitoba, where the PPS premises are located and approved the start of the operation.

The contract requires that seed from only licit sources be used. There are a limited number of legal sources of marijuana seed in the world and both the contractor and Health Canada are pursuing the acquisition of seed. Pending availability of seed from these sources, seed that is seized in Canada by enforcement agencies is being used.

Neither of the three drug control international conventions to which Canada is signatory, the *Convention on Psychotropic Substances, 1971*, the *Single Convention on Narcotic Drugs, 1961*, as amended by the 1972 Protocol, nor the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988* prohibit the use of seized seeds for the PPS contract.

Seed seized in Canada is considered acceptable as materials seized during enforcement activities are forfeited to the Crown or must be delivered to the Minister under the Act and can then be legally transferred to the licensed dealership of the Office of Controlled Substances (OCS). Under section 25 of the Act, the Minister may direct that seized cannabis seeds be transferred to the licensed dealership of the OCS once the conditions in that section have been met. The seeds are transferred from the OCS dealership to PPS which is also a licensed dealer. All Canadian requirements related to the transfer of narcotics are satisfied.

The company is expected to deliver the first product to Health Canada by early 2002.

6 FRANCE

Since 1970 's law which stipulates prohibition of cannabis even for one's personal and private utilisation, the politicians have denied main neuroscientific studies and have been keeping the same understanding and vision of cannabis, more a political than a scientific one.

Therefore, the French medical community interest in cannabis is low. The French clinical knowledge on this issue is far from important, if we exclude some AIDS specialists (orexigen effects), oncologists (anti vomiting effect), neurologists and addiction medicine specialists. Among these specialists, some deliver qualified certificates mentioning the need of cannabis use for such patients, hoping to protect them of legal proceedings.

On the opposite, actions have been initialised by NGO's, particularly enhanced by lawyer F.Caballero's action : he asked, 2 years ago, the authorisation form Health's Ministry to import cannabis for patients suffering of heavy diseases. This request was denied. More generally, self support drugs users NGOs have shown their interest for therapeutically administrated cannabis (CIRC : collectif d'information et de recherche sur le cannabis ; ASUD : auto-support des usagers de drogues).

Furthermore, a recent poll just pointed out that 68% of the French population is in favour of medicinal use of cannabis. Concerning drugs, the French population is more advanced than their own politicians.

Cannabis disappeared from French pharmacopoeia in 1953. Up to a very recent date, it was almost impossible to obtain THC in France. Nowadays, we have possibility of a nominative ATU (Temporary Utility Authorization) which is the most restrictive of ATU's possibilities: Cannabis or its derivatives especially dronabinol and nabilone do not have AMM (Autorisation de Mise sur le Marché) in France. Their medical use is only possible within a frame of clinical essays or nominative temporary use authorisation (ATU).

Untill today, there is no request of AMM concerning medicinal cannabis in France. The French Ministry of Health has taken, in June 2001, the decision to initialise a clinical essay for the following indications:

- anorexia and asthenia along hepatitis C and HIV infections
- glaucoma
- Multiple sclerosis and neurodegenerative disorders.

the protocols of these essays are yet discussed and should be proposed at the end of this year.

1) Today Statement:

One clinical essay (phase 1, with no direct individual benefit) was driven with 32 healthy volunteers during summer 2000 (promotor: Atlantic Pharmaceutical Incorporation). This clinical essay was on CT3 acid (6aR, 10aR)-4(1,1 dimethyl)-delta-8-tetrahydrocannabinol-9-carboxylic) not classified as narcotic.

2) ATU (Autorisations temporaire d'utilisation nominatives)

In France, since the beginning of 1999 the medical use of Dronabinol (Marinol) and Nabilone (Cesamet) has been authorised by the French Agency "Afssaps" as a pain relief and against nausea (in case of inefficiency of usual treatments) with nominative ATU. Up today, there has been 3 nominative ATU for Dronabinol as pain relief and 5 nominative ATU for Nabilone (1 pain syndrome in HIV infection, 4 nausea resistant, 1 hyperalgetic multiple sclerosis).

7 GERMANY

Recently the application of cannabis products as a medicine (in the following referred to as medicinal cannabis) has been discussed increasingly by specialist publications and the daily news media. From an expert point of view, the discussion is not always well-balanced and particularly questionable where:

- the call for medicinal cannabis is connected with the legalisation of Cannabis in general even including the purpose of what we call misuse
- medicinal cannabis is uncritically extolled as panacea for a multitude of even the most severe diseases,
- the marketing of medicinal cannabis is requested in strict contrast to the principles of the German Medicines Act.

In this respect we hold the following view:

1. The application of medicinal cannabis does not require in any way the general legalisation of cannabis. Both the International Conventions limiting the trade in Narcotic Drugs and Psychotropic Substances and also the German Narcotics Act, as a rule, allow the use of Narcotics and Psychotropic Substances for medical purposes. I quote Article 4 of the Single Convention on Narcotic Drugs of 1961: "The parties shall take such legislative and administrative measures as may be necessary subject to the provisions of this Convention to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs." Consequently, Section 5 para 1 No. 6 of the Narcotics Act states the purpose of this Act as "to secure the required medical care for the population, as well as to preclude the abuse of narcotics and to preclude the development or maintenance of addiction as far as possible." The efforts to make medicinal cannabis available may thus concentrate on the technical and legal aspects of the issue under discussion and should not by any means be burdened with a discussion on the legalisation of cannabis. This would not be conducive to the efforts towards making cannabis available for medicinal purposes. Last but not least, patients advocating the availability of medicinal cannabis might be discredited as potential misusers of narcotic drugs.
2. Without any doubt, medicinal cannabis has a large-scale of pharmacological effects (see, *inter alia*, footnote1. However, it has to be pointed out that information on effects of cannabis is frequently based on anecdotal reports or investigations which do not comply with the requirements for clinical trials required by the German Medicines Act. The chairman of the International Association for Cannabis as Medicine with justification and with a sense of responsibility summarises the very different scientific findings on various indications for medicinal cannabis in a "hierarchy of therapeutical effects" as follows:

"1. Well-established indications:	nausea and vomiting, anorexia and loss of weight.
2. Relatively well-established indications:	spasticity, pain, motor disturbances, asthma, glaucoma.
3. Less well-established indications:	allergies, pruritus, inflammations and infections, epilepsy, depressions, bipolar disturbances and anxiety disorders, dependence and withdrawal symptoms.

1 Goedecke, Karkos: *Die arzneiliche Verwendung von Cannabisprodukten* (The use of cannabis products as medicine, German Pharmacists' Magazine). Dtsch. Apoth. Ztg. 136, 2859-2862 (1996)

4. Basic research: autoimmune diseases, cancer, neuroprotection, fever, blood pressure disturbances."² [2]

Also the claim that the natural composition of the active ingredients has a better effect than isolated substances has not been substantiated by scientific evidence so far. However a multicentre study which was started in 1999 and co-ordinated by the European Institute for Oncological and Immunological Research Berlin could yield valid results. This study is the first clinical trial according to the German Medicines Act to examine the efficiency of cannabis extract as compared to pharmaceutical products containing isolated dronabinol for inducing appetite in cancer patients.

With this insufficient scientific evidence on hand an attempt of treatment may be justified in individual cases, but for the protection of the patient as well as the physician particular care is required in the prescription of medicines containing dronabinol. From a medical point of view the self-medication with cannabis products has to be rejected.

3. The supply of the population with medicinal cannabis must be in accordance with the German Medicines Act just as with any other medicinal product. According to these provisions, the reproducible quality, efficiency and safety of the pharmaceutical drugs used has to be proved scientifically. If these prerequisites are met, the corresponding active ingredient might be included in Schedule III of the Narcotics Act (licit narcotic drugs and available on special prescription). So far, this has been achieved for nabilone and dronabinol, two active ingredients of cannabis. In the same way, natural mixtures (e.g. cannabis extract) could be included in Schedule III if the prerequisites are met. This does not apply to hashish, marihuana and other illicit cannabis preparations. With these products, neither the content of active ingredients nor the type and extent of harmful admixtures (solvents, heavy metals, insecticides) is known. Therefore, the Federal Institute for Drugs and Medical Devices has not allowed to use this kind of untested products for medical purposes. Consequently, it should be our objective to market medicinal cannabis on the basis of the German Medicines Act.

According to the German legislation, pharmaceuticals may either be marketed as investigational drugs within the scope of a clinical trial or as finished drugs manufactured by pharmaceutical companies or as pharmaceutical drugs manufactured by pharmacies on individual prescription.

According to Section 3 para 2 of the Narcotics Act, cannabis could be used only on the basis of an appropriate authorisation "for scientific or other purposes which are in the public interest" Such an authorisation has been granted for the afore-mentioned multicentre clinical trial in May 1999 by the Federal Institute for Drugs and Medical Devices.

Finished drugs have to be granted a marketing authorisation by the Federal Institute for Drugs and Medical Devices. According to the principles set forth in the German Medicines Act, the marketing authorisation for a finished drug may only be granted to a pharmaceutical company. So far no pharmaceutical cannabis product has been authorised for marketing in the Federal Republic of Germany. However, pharmaceuticals containing the active ingredient nabilone (Cesamet) or dronabinol (Marinol) are on the market in the United Kingdom and the USA respectively. In Germany this products may be prescribed and imported in individual cases on the basis of Section 73 para 3 of the German Medicines Act. This is done to a small extent.

Individually manufactured and dispensed drugs may also be prepared in pharmacies according to a specific medical prescription, if starting materials of a defined quality are available. In principle, this is also possible for pharmaceuticals with standardised natural mixtures or

² Grotenhermen: *Cannabis und Cannabinoide* (Cannabis and cannabinoids). Verlag Hans Huber, Bern, 2001 ISBN 3-456-83220-6, p. 142.

isolated active ingredients of cannabis. Since the middle of last year, dronabinol, the primary active ingredient of cannabis, may be procured by pharmacies at defined quality from a company which has been granted an appropriate authorisation for the manufacture and distribution by the Federal Opium Agency.

At present, natural mixtures of cannabis are not yet available for the manufacture of pharmaceutical drugs in pharmacies. However, in co-operation with the Commission of the German Drug Code various companies are preparing the supply of standardised cannabis extract. In this context the listing of cannabis extract in Schedule III of the Narcotics Act is being prepared.

In summary, it can be stated that already now medicinal cannabis products containing dronabinol, the primary active ingredient of cannabis can be prescribed on a narcotic drugs' prescription form and supplied by pharmacies. In an effort to improve the supply of medicinal cannabis, we should guarantee the availability of cannabis extract for the use in pharmacies as well as work towards marketing authorisations for finished products containing cannabis.

8 THE NETHERLANDS

8.1 Legislation

a. drug legislation in general

In the Netherlands drugs are regulated by the Opium Act. It prohibits the possession, culture, preparation, distribution, import, export and other acts with the drugs listed in the annexes. The drugs mentioned in the schedules of the Single Convention on narcotic drugs and the Convention on Psychotropic Substances are all listed in these annexes. Also drugs banned on the European and the national level can be prohibited by the Opium Act. It distinguishes between different types of drugs on the basis of their harmfulness (hemp products on the one hand, and drugs that represent an "unacceptable" risk on the other).

Dealing in small quantities of cannabis, through the outlets known as coffee shops, is tolerated under strict conditions. This tolerance is a typically Dutch policy instrument which is based on the power of the Public Prosecutor to refrain from prosecuting offences. This principle is formulated in the law and is called the "expediency principle". The small-scale dealing carried out in the coffee shops is thus an offence from a legal viewpoint, but under certain conditions it is not prosecuted. These conditions are: no advertising, no sales of hard drugs, no nuisance must be caused, no admittance of and sales to minors (under the age of 18), and no sales exceeding 5 grams of cannabis per transaction. The stock of the coffee shop should not exceed 500 grams of cannabis.

The idea behind the Netherlands' policy towards the coffee shops is that of harm limitation. This is based on the argument that if we do not prosecute small-scale cannabis dealing and use under certain conditions, the users – who are mainly young people experimenting with the drug – are not criminalised (they do not get a criminal record) and they are not forced to move in criminal circles, where the risk that they will be pressed to try more dangerous drugs such as heroin is much greater.

Many people think that drugs are legally available in the Netherlands, and that we make no effort to combat the supply side of the drug market. Nothing could be further from the truth. There is continual, intensive co-operation between the addict care system, the judicial authorities and the public administrators. With the exception of small-scale cannabis dealing in coffee shops, tackling all other forms of drug dealing and production has high priority. The police and customs officials regularly seize large hauls of drugs and collaborate closely with other countries in the fight against organised crime. Last year, about 40.000 kg of cannabis and about 660.000 marihuana plants have been seized; 1372 nursery gardens have been dismantled; 5,5 million tablets of XTC have been seized. The punishability of drug-related offences is comparable with that in many other countries, and the extent to which we enforce our drug laws is also closely comparable with that in our neighbour countries. The Netherlands has one of the largest prison capacities in Europe, and 17 % of the cells are occupied by violators of our drug laws. It has been estimated that between 25% and 44% of the prison population consists of drug addicts or drug users.

b. medicinal use of cannabis

Narcotic drugs that may be prescribed and dispensed by physicians and pharmacists for medicinal purposes are listed in an annex to the Royal Decree on prescribing and dispensing of opium act substances of 1999. The prescription and dispensing of cannabis, cannabis resin and their preparations are not allowed as these substances are not in this list.³

If someone wants to grow or to give cannabis to his patients, for instance in a clinical trial, he needs a narcotic drug licence of the Office of Medicinal Cannabis (OMC, in Dutch: Bureau voor Medicinale Cannabis, BMC).

³ The prescription of dronabinol (Marinol) is allowed. This substance can be imported on a special licence of the Health Care Inspectorate.

OMC developed and published criteria how to decide on applications. These criteria refer to, among other, the screening of candidate growers and the Good Agricultural Practice (see annexes) to which growers have to comply.

8.2 Policy with regard to medicinal use of cannabis

a. History

In the Netherlands there has been a strong lobby for admitting medicinal use of cannabis for about a decade. The Health Council advised the government in 1995 that there was not sufficient evidence for the efficacy of cannabis to admit it in therapy. This advice led to the decision in 1998 to establish a government agency for the culture of cannabis, as required by the Single Convention on narcotic drugs if a state allows the culture of cannabis.

This agency was established in march 2000 and is called Office of Medicinal Cannabis (in Dutch: Bureau voor Medicinale Cannabis, BMC). It started acting as a national agency on 1 January 2001. It holds the monopoly for the Netherlands of importing, exporting, wholesale of cannabis and its preparations on behalf of the Minister of Health, Welfare and Sport. The office is notified to the International Narcotics Control Board in Vienna.

There is an amendment to the Opium Act under procedure in parliament to embed the monopoly and the powers of OMC in the law.

b. Initial track: developing a registered medicine

The primary aim of establishing such an agency is to make cannabis legally available for research purposes. We hope this will lead to a cannabis based medicine from legally grown cannabis registered at the Medicines Evaluation Board (CBG-MEB) or the European Medicines Evaluation Agency (EMA). OMC will stimulate pharmaceutical companies to develop such a medicine and it will bring interested companies, clinicians, growers and others in contact with each other. OMC will be the supplier of the cannabis needed. The cannabis will be grown by licensed growers.

c. Additional track: making the herb available as a prescription drug

Only recently the government decided that for the time that there is no registered medicine available yet, the supply of medicinal cannabis through pharmacies on a doctors prescription will be allowed. The Royal Decree on prescribing and dispensing of opium act substances will be changed in a way that it is no longer prohibited for doctors to prescribe cannabis and for pharmacists to deliver it. This will come into force as soon as the OMC has organised the legal supply of cannabis to pharmacies.⁴ This is expected in spring 2003. Because the medicinal use is still not evidence based, the cost will not be reimbursed by the public health insurance.

OMC will be the supplier and wholesaler of the cannabis needed. The cannabis will be grown by licensed growers.

8.3 Cannabis supply possibilities

As said, the Office of Medicinal Cannabis is established to supply the Dutch market with cannabis and cannabis preparations for medicinal and scientific purposes primarily. However, requests for cannabis from other countries for these purposes will be considered, provided that the authorities of the other country agree. Because the office has got several questions about this possibility, an abstract of what is available is given below.

⁴ The legal base for the distribution of cannabis by pharmacists is the possibility in European pharmaceutical law for magistral and extemporaneous preparations. This means that the pharmacies can make their own preparations for their own patients. They can keep self-prepared medicines in stock (magistral preparations) or prepare them for an individual patient (extemporaneous preparations). These preparations do not need to be registered. About 6% of all prescriptions in Dutch pharmacy practice are magistral or extemporaneous. Examples are tailor made suppositories, capsules, creams and ointments. In the field of herbal medicine it can be compared with Camomile blossom (*Matricaria flos*) or Java tea (*Orthosiphonis herba*), but with a difference that these both latter herbal drugs do not need a prescription.

Because the Office is newly established it is still in the circumstance that it has to set up the rules, licenses and organisation for the production and wholesale of cannabis for scientific and medicinal purposes. Not all varieties will be available immediately. Not all varieties are shown in the table; please contact us if you have special requirements.

Code	Cold extraction			Pre-heated (2.5 hours at 100 C)				Price per gram in EUR ** no VAT included
	cannabidiol	cannabinol	Δ-9 THC	cannabidiol	cannabinol	Δ-9 THC	Moist*	
	(mg/100g dry weight)	(mg/100g dry weight)	(mg/100g dry weight)	(mg/100g dry weight)	(mg/100g dry weight)	(mg/100g dry weight)	%	
High THC-varieties								
MGC #1001***	<500	<500	<1500	<500	<1000	10200±500	n.a.	5,86
simm 2	<10	38	522	<10	91	10711	12,8	4,49
simm 13	<10	61	936	<10	124	11193	12,9	5,67
simm 6	<10	86	1000	<10	143	12695	12,7	5,67
simm 7	<10	46	1918	<10	134	12787	17,4	4,49
simm 5	<10	88	755	<10	129	15257	15,1	5,67
simm 12	<10	122	1283	<10	203	18218	18,2	3,86
simm 10	<10	155	767	<10	194	18729	13,0	3,86
simm 17	<10	135	1569	<10	192	18735	12,9	4,31
simm 18	<10	137	2894	<10	223	19033	12,7	3,86
simm 15	<10	89	1882	<10	143	19845	13,4	9,53
Low and medium THC-varieties								
P18	<10	<10	21	<10	26	478	13,6	9,08
P14	<10	416	2941	<10	604	2010	0,8	9,08
P20	<10	<10	462	257	114	3973	9,5	9,08
P10	<10	54	622	<10	167	4372	15,4	9,08
simm 11	<10	<10	1952	<10	52	7601	81,7****	3,86
simm 4	<10	28	850	<10	67	9002	13,2	3,56
CBD-varieties								
P22	1807	12	90	2322	13	75	10,0	9,08
P15	2103	29	96	3033	19	84	12,9	9,08
Placebo breeds								
P18	<10	<10	21	<10	26	478	13,6	9,08
Placebo "P"*****				<100	<500	<100	n.a.	14,62

n.a. not available

* Moist contents can vary. These figures are shown as examples.

** For Simm codes and P-codes minimum delivery 1000g. For smaller amount add 20% to the price shown

*** Sterile (gamma-rayed) product

**** Fresh sample

***** Contents: expected figures. Price shown for amounts of at least 1000g.

OMC intends to develop a monograph on cannabis with uniform standardised methods of analysis and criteria for approval, which is applicable to all products from all our growers.

Application of the Guidelines for cultivating cannabis for medicinal purposes (see annex), which are rules of Good Agricultural Practice, will be required from the grower by OMC. These rules are to ensure that the cannabis is of constant quality and reproducible. They include the standardisation of the culture through means of standardisation of growing conditions.

Because production has not yet started, time of delivery can not be guaranteed during about the next half year. It is dependent of the period needed for licensing of the grower (about 3 months), the culture period and, if necessary, additional requirements for licensing of the Office of Medicinal Cannabis. It is estimated to be 7 months. Thereafter orders can be delivered in 15 weeks at maximum.

9 NORWAY

9.1 Legislation and practical solutions

So far there has been no legislation, existing or suggested, specifically for medicinal cannabis. For cannabis products, which are considered as drugs of abuse, the Norwegian Drug legislation applies:

There are no separate laws relating only to drugs in Norway. All illicit dealings with drugs are covered by the Norwegian Civil Penal Code of 22 May 1902, with the exception of the use and possession of minor quantities of drugs, which is penalised through the Act on Medicinal Products etc. of 4 December 1992, with regulations. As far as control policy is concerned, the Norwegian legislation admits the maximum penalty of 21 years of imprisonment to be applied for serious drug crimes.

The legal provisions concerning care and treatment are laid down in the Social Services Act of 13 December 1991, no 81, chapter 6 – Special Measures for Alcohol and Drug Abusers.

9.2 Controlled substances

The *Civil Penal Code* and the *Act on Medicinal Products* do not define the term "drugs". The *Act on medicinal Products* no. 132 of 4. December 1992, in § 22 empowers the King to determine what substances shall be deemed to be narcotic drugs. The king has then empowered the Director of Health (as from 1 January 2001 the Norwegian Medicines Agency) who has laid down a detailed list of narcotics, cf. The Regulation relating to narcotics etc. (The Narcotics' list of 30. June 1978, no 8). Included in the national narcotic drug list are all the psychotropic substances (cf. Convention on Psychotropic Substances) and narcotic drugs (cf. Single Convention on Narcotic Drugs) under international control and in addition a few substances/plants, which are only under national control. Salts and derivatives of the substances listed in the national narcotic drug list, and any isomers, esters and ethers of the substances or their are also considered narcotic drugs.

The Regulation of 19 December 1997 concerning Certain Substances that can be used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances, precursors, implements the European Directive n° 92/109 of 14 December 1992.

9.3 Drug use and possession

The legal status of use and possession of small amounts of drugs changed from misdemeanour to crime in 1984. Use and possession of such small amounts do not, however, fall under § 162 of the General Civil Penal Code, but under the more lenient provisions of the Act on Medicinal Products of 4. December 1992, no 132, § 31 second paragraph, cf. § 24. The punishment is fines or imprisonment for up to 6 months. The same applies to complicity. Attempted infringement will be punished as an accomplished offence cf. § 31, last paragraph.

It must be explained that the law divides between *storage* which falls under § 162 of the Civil Penal Code, and *possession* which falls under § 31 of the Act on Medicinal Products, cf. § 24. The purely temporary possession required for a person to use certain illegal drugs falls under the Act on Medicinal Products, § 31, second paragraph. On the contrary, if possession has been going on for some time it will be considered as storage and punished more severely in accordance with § 162 of the Civil Penal Code.

In cases where a person is apprehended with a considerable quantity of drugs, it is likely that such possession will be regarded as storing regardless of whether the drugs were intended for sale or just stored for personal consumption.

”Acquisition of drugs” falls under § 162. But if acquisition and consumption are *one and the same*, i.e., if another person gives someone a syringe containing morphine or a pipe containing hashish, the more lenient provisions of the Act on Medicinal Products shall apply.

9.4 Trafficking and drug related crime

The Civil Penal Code § 162, first paragraph is the main provision with regard to drug felonies. It relates to anyone who intentionally (cf. § 40 of the General Civil Penal Code) ”manufactures, acquires, imports, exports, stores, sends or conveys” narcotic drugs. *The penalty* for drug offences pursuant to 162, first paragraph is fines and/or imprisonment up to 2 years. *Aggravated drug felonies* however, are punished by a term of imprisonment not exceeding 10 years pursuant to the second paragraph of this provision. Whether an offence is to be considered aggravated will depend on a special evaluation in each case where, according to statutory provisions, special importance shall be attached to what sort of substance is involved, its quantity and the nature of the offence (i.e. if the substance has been systematically sold to groups which are considered to be especially vulnerable, such as pupils, inmates in prisons and clients in social institutions).

The third paragraph increases the penalty to a term of imprisonment of no less than three and not more than 15 years if ”a very considerable quantity is involved in the offence”. According to the intentions behind this provision, it shall only be applied in very exceptional cases. Under ”very aggravating circumstances”, a term of imprisonment not exceeding 21 years may be imposed pursuant to the second paragraph, item 2. From the legislative history behind this provision, it is clear that it was mainly intended to harm the really large organisers of international drug trafficking involving the most dangerous drugs.

Fines and/or imprisonment for a term not exceeding two years shall punish negligent violation of § 162. Complicity in a drug offence shall be punished in the same way as the main offence.

9.5 Prosecution and judicial practice

Practice shows that the penalty for drug felonies to a large extent depends on the substance and quantity involved. Involvement with cannabis (hashish) is subject to far more lenient sentencing than involvement with more dangerous substances. Also a very important issue with regard to sentencing is the nature of the involvement that the convicted felon has had with the substance. The reactions are normally far more lenient in cases involving the import and purchase of drugs intended for personal consumption than in cases where the act was motivated by profit.

In three recent court decisions (Rt. 1999, p.33 and p. 1504 and the Supreme Court Ruling of 6. September 2000), the Supreme Court very strongly expresses the need to draw a distinct line between the purchase and storing of drugs intended for private consumption and the purchase and storing of drugs intended for sale. In the Supreme Court Ruling from September 2000, the first voting justice stated that this decision, in his opinion ”must be perceived as being an indication of a change of practice” compared to earlier. It may therefore seem like the Supreme Court wants to go to even further than it previously has, in creating a distinction between involvement with drugs intended for private consumption and involvement with drugs intended for sale.

From what has been presented above it is clear that cannabis in Norway is in principle considered to be a drug of abuse, and that no official differentiation between ”hard” drugs and ”soft” drugs exists. In practice however, cannabis-related offences might be subject to ”softer” reactions from the society, as also discussed above.

There have been very few cases during the last 5 years where single subjects (with or without support from lawyers/physicians have asked the Norwegian Board of Health (CNBH) for permit to use cannabis products as treatment for disease. NBH has the authority to grant such permits, but has so far, as far as we know, never allowed medicinal use of cannabis.

9.6 Political circumstances

The general attitude appears to be that when it can be documented that medicinal cannabis can be shown to be a better alternative than existing therapies for any patient group (therapeutic effects/and side effects considered) there will be little opposition against its release and use for this purpose. The prerequisite for this is that medical experts in that particular field of medicine actually feel convinced to recommend such therapy. So far this has not been the case in Norway.

10 SWITZERLAND

10.1 The Swiss drug policy

In view of the increasing drug problem in the eighties, the federal government decided in 1991 to intensify its commitment considerably in this area, focussing on the following objectives:

- To reduce the number of new users/addicts
- To increase the number of addicts, that quit addiction
- To reduce damage to the health and social integration of users/addicts
- To protect society from harmful effects of the drug problem and to fight against organised crime

In order to achieve these objectives, the federal government is pursuing a policy comprising four strategic elements (fourfold approach of the drug policy): (1) Law enforcement, (2) Prevention, (3) Therapy, (4) Harm Reduction.

10.2 Status of the political situation

In 1993 and 1994, two referendums were presented, with opposite objectives.

The referendum entitled „Youth without Drugs“ called for a strict, abstinence-oriented drug policy that contained elements of repression, prevention and therapy. Swiss voters rejected the referendum with a majority of 71 percent following the recommendation of government and parliament.

The referendum entitled „For a Reasonable Drug Policy“ proposed the opposite, namely the decriminalisation of drug use, cultivation of plants used to produce drugs, possession of drugs and purchase of drugs for personal use. Swiss voters rejected the referendum, too, with a majority of 73%, following the recommendation of government and parliament.

The Swiss population has in both cases shown its massive support for the government's pragmatic fourfold approach. The outcome of these two referendums showed that – after many years of discord – a consensus could be reached concerning the drug policy to be followed in Switzerland.

Revision of the federal law on narcotic drugs and psychotropic substances, from 1951

On March 9, 2001 the seven members of the Federal Government decided to submit a proposal for revising the Swiss federal law on narcotic drugs and psychotropic substances from 1951 to Parliament. This proposal is the result of a broad consultation amongst cantons, political parties and special interest groups in the fields of economy, health, social welfare, law enforcement and others.

Parliamentary debate upon this proposal will not begin before fall or winter this year and is expected to extend at least until summer or fall of 2002, since the two houses of Parliament will have to reach consensus after having considered the project individually.

Should 50'000 voters in Switzerland not approve of the final decision of the Parliament, they can ask for a national referendum, which would probably be voted upon in 2003.

The revision of law proposed by the Government confirms the general orientation of Swiss drug policy with its main objectives:

- reduce the number of new drug users and addicts,
- increase the number of individuals who succeed in overcoming drug dependence,
- reduce the damage to the health of drug addicts and their marginalisation in society,
- protect society from the negative effects of the drug problem and
- combat drug related crime.

In order to achieve these objectives the national strategy which consists of a fourfold approach, that has been developed and successfully implemented over the last ten years, will be outlined in the revised law. In particular the four key elements of the national strategy – prevention, therapy, harm reduction and law enforcement – will be explicitly mentioned. Moreover, heroin assisted treatment will be formally included as part of the therapeutic measures available, special provisions to protect young people from drug dependence will be introduced and the coordinating role of the federal administration will be confirmed.

All these changes will enlarge the overall scope of the law: in addition to the objectives of drug control and combat of drug related crime, clear emphasis will be put on public health aspects.

10.3 The new cannabis policy in Switzerland

A partly new orientation is proposed for addressing the various issues concerning cannabis. Personal use of cannabis and its most closely related preparatory acts will no longer be criminal offences. Cultivation, production, manufacture and trade of cannabis will remain prohibited. However, in accordance with Article 3, Paragraph 6 of the 1988 UN Convention against illicit traffic in narcotic drugs and psychotropic substances the revised Swiss law on narcotics will enable the Federal Council to define clear priorities for the prosecution of drug offences (discretionary prosecution). The legislator will restrict discretionary prosecution to the cannabis-related offences mentioned above and to personal use offences for all substances other than cannabis. The law will furthermore stipulate the kind of prerequisites it deems necessary in order to abstain from prosecution.

Concretely this could mean that trade would be tolerated if cannabis were not sold to people younger than 18 years, if no advertising takes place, if public order is not disturbed and if not more than 5 grams of cannabis are sold at a time. Cultivation on a small scale would be tolerated if intended for the local market only.

Switzerland will undertake all the necessary steps to avoid negative consequences for neighboring countries, especially export of Swiss cannabis and drug tourism. Particular efforts will be made in order to inform about the changes that will take place in Switzerland and to ensure close cooperation with the border regions of our neighboring countries.

10.4 The medical use of cannabis and its active ingredients

Today, any traffic in cannabis or in its products is prohibited (import, export, manufacture, consumption, prescription etc.) in Switzerland. Cannabis, its products, and all isomers of tetrahydrocannabinol are classified as so-called forbidden substances.

Under severe restrictions, scientific research (e.g. clinical trials) with cannabis, cannabis products and tetrahydrocannabinol can be authorized by the Swiss Federal Office of Public Health. In addition, a limited medical use (e.g. compassionate use) may be authorized for tetrahydrocannabinol and its isomers (Marinol®).

Until today, the Swiss Federal Office of Public Health authorized the compassionate use of Marinol® (Dronabinol) in 50 cases. Clinical studies are authorized for Marinol®, cannabis extracts and herbal cannabis (appetite in cancer patients, spasticity in paraplegics, spasticity in MS patients, analgesia,

cancer patients in palliative treatment). Furthermore, a research institute is allowed to grow cannabis plants and to manufacture standardized cannabis extracts.

The prescription and medical use of herbal cannabis or cannabis extracts is not yet allowed. With the revision of the federal law on narcotic drugs and psychotropic substances from 1951, it is envisaged to allow a limited medical use for herbal cannabis and cannabis extracts under the supervision of the Swiss Federal Office of Public Health.

Should the results of clinical trials with dronabinol be promising, a re-scheduling of delta-9-tetrahydrocannabinol and its stereochemical variations may be possible to allow the medical use, further research and the registration of pharmaceuticals based on cannabis or synthetic dronabinol.

11 UNITED KINGDOM

11.1 Legislation

The United Kingdom (UK) is a signatory to the United Nations Single Convention on Narcotic Drugs 1961. The UK's domestic legislation on controlled drugs is based on the Convention and provides for cannabis to be identified as a "designated drug". Section 7(3) of the Misuse of Drugs Act 1971 provides for Regulations to be made to allow the use for medical purposes of the drugs, which are subject to control under the Act. These Regulations in effect authorise activities, which would otherwise be unlawful under the Act. For example, the Regulations make it lawful for medical professionals to possess controlled drugs when acting in their professional capacity. However, these Regulations would still not permit the use of cannabis for medicinal purposes. To enable that to happen Regulations under Section 7(4) of the Act are required to be made to "designate" cannabis as a drug to which the Regulations under Section 7(3) would then apply. Such a Regulation was made in 1986. This has enabled cannabis to be cultivated/manufactured, supplied, possessed and prescribed under licence by the Home Secretary in the public interest but only for the purposes of research or other special purposes. This includes research into the production of a medicinal product containing cannabis based medicinal extract for the treatment of organic illness or injury.

A licence to cultivate cannabis plants has been issued to a UK company, GW Pharmaceuticals at a secure greenhouse complex. The complex is provided with an external alarmed perimeter fence as well as internal infra-red movement and contact detectors. Some 10,000 to 13,000 plants of different varieties, some containing active ingredient, are in cultivation at any one time. The plants were originally grown from seed and subsequent plants cloned from the parent plants.

11.2 Studies

11.2.1 GW Pharmaceuticals (GWP)

Their prime objective is to develop non-smoked prescription medicines derived from pharmaceutical grade extracts of specific chemovars (chemically defined varieties) of the cannabis plant to meet patient needs in a wide variety of medical conditions. Medicines containing extracts from the plants grown at the complex have been produced in the form of a sublingual aerosol spray. Licences for doctors to prescribe that cannabis based medicinal extract in clinical trials have been issued.

In order to obtain regulatory approval for a prescription medicine, it is necessary to undergo Phase I, II and III trials as follows: -

Phase I – conducted in healthy volunteers to provide evidence of safety. The trial also examines the pharmacokinetic profile of the drug – the absorption, distribution, metabolism and excretion of the drug by the human body and its biological effects on humans. The first Phase I trial was carried out in September 1999 and a second one was carried out in May 2000. The intention is that Phase I trials will continue throughout the development programme.

Phase II – conducted in a limited number of patients to assess short-term safety and preliminary efficacy. Appropriate dose ranges and regimens for Phase III trials are also determined. Clearance for these trials was granted by the Medicines Control Agency (the UK's regulatory authority) in April 2000 and trials are currently taking place at multiple hospitals.

Phase III – comprehensive evaluation of safety and efficacy in large numbers of patients. This phase commenced earlier this year and led straight into large-scale studies. The regulatory dossier for the first major product approval is expected to be ready by 2003 with the hope of marketing in early 2004.

11.2.2 Cannabis in Multiple Sclerosis (CAMS) Study

The Medical Research Council is funding this clinical trial to assess the therapeutic effect of cannabis extract in multiple sclerosis. Patients receive one of three treatments, as oral capsules: extract of cannabis (“Cannador”), THC (“Marinol”) or a placebo. As you are probably aware, the Cannador product is imported from Germany where Swiss grown material is capsuled.

The trial, which commenced in April 2001, allows 15 weeks for a full evaluation study. On completion of the main study, patients will be offered entry into a long-term follow-up study of continued efficacy and safety if they found their therapy beneficial. Patients will continue to be monitored on a three-monthly basis for a further year.

So far, 122 patients have taken part in the GWP trial at twelve different sites. Numbers will continue to increase steadily as patients are recruited to studies and new studies start. It is intended that the CAMS study will have a patient population of 660 at 30 different sites.

GW Pharmaceuticals is developing non-smoked delivery methods that produce rapid absorption via the respiratory tract and oral mucosa. A sub-lingual spray is being used in the current trials.

As mentioned above, the CAMS study is restricted to the swallowing of 2.5mg capsules. Two of the treatments contain active drugs whilst the third is a placebo. Patients are chosen on a randomised basis.

Dosage levels and rates for the GWP study vary depending on the type of individual trial undertaken. The target dosage for the CAMS trial is between 2 and 4 capsules twice a day.

Every stage of both trials is strictly controlled under Home Office licence. For the GWP study this covers the cultivation of the plant, the production of the various cannabis based medicine extracts, the manufacturers of the various delivery systems, the doctors carrying out the trials and their patients. The CAMS trial is dependent on the import of the Cannador and Marinol capsules, which can only take place under licence, and, as with the GWP study, doctors and patients are also licensed.

12 ANNEX I: Relevant articles from the Single Convention on Narcotic Drugs

SINGLE CONVENTION ON NARCOTIC DRUGS, 1961, AS AMENDED BY THE 1972 PROTOCOL AMENDING THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961

Here is a selection of articles 23 and 28 of the Single Convention on Narcotic Drugs, 1961 of the United Nations. If you are interested in reading the complete convention, please check www.incb.org/e/ind_conv.htm

Article 23

NATIONAL OPIUM AGENCIES

1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.
2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium;
 - (a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.
 - (b) Only cultivators licensed by the Agency shall be authorised to engage in such cultivation.
 - (c) Each licence shall specify the extent of the land on which the cultivation is permitted.
 - (d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.
 - (e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.
3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

Article 28

CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.
2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

13 ANNEX II: Guidelines for cultivating cannabis for medicinal purposes (The Netherlands)

1 Introduction

Under certain conditions, the Dutch government permits the cultivation of cannabis for medicinal purposes. In the case of herbal drugs, the cultivation method and primary processing of the plant determines the ultimate properties of the active pharmaceutical ingredient. Starting materials of herbal origin have a complex composition and can only be characterised to a limited extent through chemical or biological analysis. Therefore, an effective quality assurance system in the steps leading up to the production of the active pharmaceutical ingredient is needed in order to guarantee reproducible quality. These steps are cultivation, harvesting and primary processing.

The following guidelines for cultivating, harvesting and primary processing of cannabis constitute a quality assurance system that meets these requirements. The Office of Medicinal Cannabis (Bureau voor Medicinale Cannabis) will test on the basis of these requirements.

These guidelines have been derived from the general rules for Good Agricultural Practice of the Working Group on Herbal Medicinal Products of the European Medicines Evaluation Agency (EMA).

This is a non-authorised translation of the official version in Dutch.

2 General

2.1 These guidelines apply to the cultivation, harvesting and primary processing of cannabis plants intended for medicinal use or the preparation of medicinal drugs. These guidelines must be read in connection with the European Good Manufacturing Practice (GMP) guidelines for active pharmaceutical products. They apply to all methods of production including organic cultivation. These guidelines also provide additional standards for the production and processing of herbal starting materials insofar as they identify the critical production steps that are needed to ensure good, reproducible quality.

2.2 The main objective of these guidelines is to increase the reliability of the medicines prepared from cannabis by establishing an appropriate quality standard for the herbal medicine cannabis. In particular, it is important that the cannabis:

- is produced hygienically to keep microbiological contamination to a minimum;
- is produced such that negative effects on the plants during cultivation, processing and storage are kept to a minimum;
- is produced under conditions that ensure that the therapeutic properties of the end product are constant and reproducible.

3 Personnel and training

3.1 Training

3.1.1 Personnel must have received adequate botanical/horticultural training before performing the tasks given to them.

3.1.2 Production personnel must be trained in the production techniques used and the correct use of herbicides and pesticides.

3.1.3 Primary processing procedures must comply with the regulations on food hygiene.

3.2 Hygiene

- 3.2.1 All personnel entrusted with handling the herbal material must maintain proper personal hygiene (including field personnel).
- 3.2.2 Persons suffering from infectious diseases transmittable via food, including diarrhoea, or carriers of these diseases must be forbidden access to areas where they could come into contact with the herbal material.
- 3.2.3 Persons with open wounds, inflammations and skin-infections must be suspended from areas where they could come into contact with herbal material, unless they wear protective clothing or gloves until they have recovered completely.
- 3.2.4 Personnel must be protected from contact with toxic or potentially allergenic herbal material by means of adequate protective clothing.

4 Buildings and facilities

- 4.1 Buildings used in the processing of harvested crops must be clean, well ventilated and must never be used for livestock breeding.
- 4.2 Buildings must be designed in a manner that protects the crops against pests and domestic animals. Suitable pest control measures must be in place in all storage rooms and rooms where crops and products are processed and packaged, for instance electrical insect-killing machines. These must be operated and maintained by professionally qualified persons.
- 4.3 The medicinal cannabis must be stored:
 - in buildings with concrete or similar floors which are easy to clean;
 - on pallets;
 - at a sufficient distance from walls;
 - well separated from other crops in order to prevent cross-contamination.Organic products must be stored separately from products not grown organically.
- 4.4 Buildings where plant processing is carried out must have changing facilities, toilets and hand-washing facilities.

5 Equipment

- 5.1 Equipment used in plant cultivation and processing must be easy to clean in order to eliminate the risk of contamination.
- 5.2 Equipment and machinery should be mounted such that they are easily accessible. Machines used in fertiliser and pesticide application must be calibrated regularly.
- 5.3 The equipment must be made from materials other than wood. If wooden materials (such as pallets) are used, they must not come into direct contact with chemicals and contaminated materials, in order to prevent contamination of the herbal materials.
- 5.4 Equipment and machinery used for harvesting must be clean and in very good working condition. Machine parts that come into direct contact with the harvested crop must be cleaned regularly and must be free from oil and contamination, including residual plant matter.

6 Seeds and propagation material

6.1 Seeds and propagation material must be botanically identified as to species, variety, chemotype and origin. The materials used must be traceable. Starting material must be free from pests and disease as much as possible in order to guarantee healthy growth.

6.2 During the entire production process (cultivation, harvest, drying, packaging), the presence of different species, varieties or different plant parts must be monitored. Any impurities must be removed immediately.

7 Cultivation

7.1 Soil and fertilisation

7.1.1 Cannabis for medicinal purposes must not be grown on soil contaminated with sludge, heavy metals, pesticide residues or other chemicals. Any chemicals used must therefore be kept to the minimum effective dose.

7.1.2 Manure applied should be thoroughly composted and must be devoid of human faeces. Irrigation should be controlled and according to the needs of the cannabis plant. Fertilisers should be used in such a way that leaching is reduced to a minimum.

7.2 Irrigation

7.2.1 Irrigation must be controlled and only as required by the cannabis plant.

7.2.2 Irrigation water must be free from contaminants like faeces, heavy metals, herbicides, pesticides and toxicologically hazardous substances.

7.3 All tillage must be adapted to plant growth and requirements. Using herbicides and pesticides must be avoided as far as possible. Use and storage of pesticides must be in accordance with the recommendations of the manufacturer and the relevant approval authorities. Only qualified personnel are allowed to use such substances using only approved material but not in a period preceding the harvest, as indicated by the buyer or producer.

8. Harvesting

8.1 Harvesting must be done when the plants have reached the best quality for the intended use.

8.2 Male, damaged, and dead plants must be removed.

8.3 Harvesting must take place under the best possible conditions, avoiding wet soil, dew, rain or extremely high air humidity. If harvesting occurs in wet conditions, additional care needs to be taken to avoid the adverse effects of moisture.

8.4 During harvesting, care must be taken that no other plants/weeds get mixed with the cannabis crop.

8.5 The harvested crop must not come into direct contact with the soil. Directly after harvesting, it must be prepared for transport in clean, dry conditions (e.g. sacks, baskets, boxes).

8.6 All containers must be clean and free from any residues from previous harvests; containers that are not in use must be kept in dry conditions, free of pests and inaccessible to domestic animals.

8.7 Mechanical damage and compacting of the herbal drug that could result in undesirable quality changes must be avoided. In this respect, take care to avoid:

- overfilling sacks/containers;
- stacking sacks/containers too high.

8.8 Freshly harvested herbal material must be delivered to the processing facility as quickly as possible in order to prevent thermal degradation.

8.9 The harvested crop must be protected from pests and domestic animals.

9 Primary processing

9.1 Primary processing includes washing, cutting before drying, decontamination from pests, freezing, distillation, drying, etc.

9.2 On arrival at the processing facility, the harvested crop must be directly unloaded and unpacked. Prior to processing, the material must not be exposed to direct sunlight (except in cases that specifically require this) and must be protected from rain.

9.3 Drying crops directly on the ground or under direct sunlight must be avoided.

9.4 Waste bins must be available and must be emptied and cleaned daily.

10 Packaging

10.1 Following repeated controls and removal of any sub-standard material or undesired objects, the product must be packaged in clean, dry and preferably new packaging. The label must be clear, firmly fixed and made from non-toxic material.

10.2 Reusable packaging material must be well cleaned and dried prior to use.

10.3 Packaging material must be stored in a clean, dry place that is free of pests and inaccessible to domestic animals. The packaging material must not contaminate the product.

11 Storage and distribution

11.1 Dried, packaged products and extracts must be stored in a dry, well-ventilated building in which daily temperature fluctuations are limited and good ventilation is ensured. Fresh products must be stored between 1°C and 5°C; frozen products must be kept at temperatures below -18°C (or below -20°C for long-term storage).

11.2 In the event of bulk transport, it is important to ensure dry conditions. To prevent mould formation or fermentation, it is advisable to use ventilated containers, transport vehicles and other ventilated facilities.

11.3 Decontamination of the storage area to combat pests must be carried out only where necessary and by authorised personnel only.

11.4 When frozen storage or saturated steam is used for pest control, the moisture content of the product must be controlled after treatment.

12 Special provisions for the production of cannabis intended for processing into a standardised herbal drug.

12.1 Herbs

- a. In these guidelines a herbal medicine is understood to mean any medicine that contains exclusively herbal drugs or herbal preparations as active ingredients.
 - b. Herbal drugs are plants or parts of plants in an unprocessed state which are used for medicinal or pharmaceutical purposes. A herbal drug or a preparation is regarded as one active substance in its entirety whether or not the constituents with therapeutic activity are known.
 - c. Herbal drug preparations are comminuted or powdered herbal drugs, extracts, tinctures, fatty or essential oils, expressed juices, processed resins or gums, etc. prepared from herbal drugs, and preparations that are produced through fractionation, purification or concentration.
 - d. In departure from the above, chemically defined isolated constituents or their mixtures are not considered herbal drug preparations.
 - e. Herbal drug preparations may contain other components such as solvents, diluents and preservatives.
- 12.2 If the cannabis is intended for processing into a standardised herbal medicine, the cannabis must be cultivated under such standardised conditions that the content of the constituents is constant.
- 12.3 The content of the main constituents, which includes Δ -9-tetrahydrocannabinol (Δ -9-THC) and cannabidiol (CBD), is determined quantitatively. For a selection of the other constituents, fingerprinting with a suitable technique, such as GC-MS, GC, HPLC or TLC will suffice.
- 12.4 Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during cultivation:
- a. cultivar of the cannabis plant;
 - b. cultivation substrate;
 - c. day length;
 - d. light intensity;
 - e. colour temperature of the lighting;
 - f. atmospheric humidity;
 - g. temperature;
 - h. ventilation;
 - i. plant age at the time of harvesting;
 - j. time of day of harvesting.
- 12.5 Unless it is proven that omitting the standardisation of one of the following elements results in a constant and reproducible product, at least the following must be standardised during drying:
- a. atmospheric humidity;
 - b. temperature;
 - c. ventilation.
13. Documentation
- 13.1 All processes and procedures which may affect the quality of the product must be recorded in the documentation for each batch. The following in particular must be documented:
- a. the location of cultivation and the name of the cultivator in charge;
 - b. details on crops previously grown at that location;
 - c. nature, origin and quantity of the herbal starting materials;
 - d. the chemicals and other substances used during cultivation, such as fertilisers, pesticides and herbicides;
 - e. standard cultivation conditions, if applicable;
 - f. particular circumstances which occurred during cultivation, harvesting and production which may affect the chemical composition, such as plant diseases or

temporary departure from standard cultivation conditions, particularly during the harvesting period;

- g. nature and quantity of the yield;
- h. date or dates, and time or times of day when harvesting occurred;
- i. drying conditions;
- j. measures for pest control.

13.2 Location

13.2.1 All batches originating from one location must be clearly labelled (e.g. with a batch number). This must be done as early on in the process as possible.

13.2.2 Batches originating from different geographic locations may only be combined if guaranteed to be the same, and that the mixture is homogenous. Mixing of batches must be documented.

13.3 It must be recorded in the documentation for each batch that the cultivation, harvest and primary processing procedures were in accordance with these requirements.

13.4 All parties involved in the production process must demand that their suppliers document all relevant stages and elements of the production process for each batch.

13.5 Audit results must be recorded in an audit report. The audit report and concomitant analysis reports and other documents must be kept for at least ten years.

14 Safeguarding the material

14.1 The buildings in which the cannabis is cultivated, processed, packaged and stored must be sufficiently secured. This means that there must be security in force and that only authorised personnel is allowed access to the buildings.

14.2 The personnel involved in the production process of cannabis must be authorised for that purpose by the employer. When concluding the supply contract, the supplier designates authorised persons and indicates how this will be verified.

14.3 There must be a balanced administration of the cannabis.

Cannabis waste must be stored in lockable containers or rooms; this must be verifiable.

14 ANNEX III: Inventory of recent and ongoing trials with cannabis

drawn up by countries (version: 10 December 2001)

1. The Netherlands

As from 1 January 2001 The Netherlands has a National Agency that aims at promoting the establishment of at least one registered medicine, prepared from legally cultivated cannabis. The establishment of the Office of Medicinal Cannabis (OMC) flows out of provisions in the Single Convention on Narcotic Drugs that apply for countries that permit cultivation of cannabis for medical and scientific purposes.

Investigations in the Netherlands:

1.1 TNO

TNO has held an inquiry among all multiple sclerosis patients in the Netherlands. The response was approximately 50 %. It appears from the answers that 12 % of the patients use cannabis for medical reasons. It was stated that smoking is more effective than oral ingestion. The Dutch MoH has granted a subsidy to TNO-P&G for more detailed analysis of the data.

This year (2001) TNO started a up studies on cannabis receptor binding and a study on the development of an optimal placebo plant.

1.2 AZVU (Polman/Killestein)

Pilot study (Cannador – Marinol – placebo). The study was completed in 2000 and showed that oral administration of medicinal cannabis has no positive effect on, among other things, spasticity in multiple sclerosis patients. It is accepted for publication in *Neuropharmacology* (author: Killestein)

A similar study is to be started in 2002 on spasticity in MS patients. This time the study will be inhaled cannabis varieties, that will be comparable to Cannador, Marinol an placebo in THC and CBD composition.

2 Canada

Canada is the only country apart from the Netherlands that has set up a national bureau for the cultivation and study of medicinal cannabis. Canada has drawn up a contract with a grower and will buy up the entire crop. However, at the moment there is no talk of production as there are still no seeds available.

In 1999 Canada announced three major projects that are to be started as soon as standardised medicinal cannabis is available.

1. A Request for Proposal (RFP) was jointly developed by Health Canada and the Canadian Institutes of Health Research (CIHR). To date one research project has been approved for funding under this program. The study, funded by Health Canada through a \$235,000 grant, is scheduled to begin in early 2002. It will be conducted under the direction of Dr. Mark Ware, McGill Pain Center of the Montreal General Hospital site of the McGill University Health Centre, McGill University. It will investigate the safety and efficacy of smoked marijuana on chronic neuropathic pain.

2. Health Canada is also supporting, through a contribution agreement, the work of the Community Research Initiatives of Toronto (CRIT) towards the undertaking

of a clinical trial. A research protocol was developed by CRIT in collaboration with the Clinical Trial Network and recently obtained regulatory approval from Health Canada. The trial will involve the assessment of smoked marijuana on appetite in persons living with HIV/AIDS and will be conducted by the Community Research Initiative of Toronto (CRIT) at St-Michael's Hospital in Toronto.

3. Clinical trial not funded by Health Canada: GW Pharmaceuticals Ltd., a UK company, issued a press release on August 14, 2001 announcing the conduct of a clinical trial at the Ottawa Hospital using pharmaceutical products derived from cannabis. The trial was approved under the requirements of the Food and Drug Regulations applicable to the conduct of clinical trials by Health Canada. The trial is currently being conducted at the Ottawa Hospital under the supervision of Dr. Daniel DeForge. Permission was obtained from GW to allow Health Canada to release the above information on the approved trial.

3. United Kingdom

The UK has no national bureau but is looking closely at the reaction of the INCB to the announcement of OMC by the Netherlands.

In the United Kingdom there is a pharmaceutical company, GW Pharmaceuticals, that carries out studies with medicinal cannabis on all sorts of complaints. GW have themselves stated that they may have a medicine on the market in 2003. GW is collaborating very closely with the Home Office (Ministry of Internal Affairs) and the Inspectorate. The UK certainly anticipates that it will have to set up a national bureau when registration of a medicine becomes necessary.

3.1 Multiple sclerosis

- Study led by Dr. Patrick Fox and Dr. John Zajicek, Derriford Hospital, Plymouth. The study has just started. Contact: Medical Research Council. Study on the effects of cannabis capsules (Cannador – Marinol – placebo) on spasticity and general wellbeing. 600 patients in a large number of hospitals. Supported by the British Medical Association and the British Government (£950,000). Results are expected by summer 2003.
- Phase 2/3 studies (begun in May 2000) on use of standardised cannabis in MS, spinal cord injury and neurological dysfunction; 200 to 300 patients.
- Nystagmus in MS (begun in May 2000)
- Bladder dysfunction in MS (started in Summer 2000).
Preliminary results of clinical research conducted in the UK and in Switzerland show that cannabis and THC are able to reduce hyperactivity of the bladder in patients with multiple sclerosis and spinal cord injury. The British study conducted at the National Hospital for Neurology and Neurosurgery in London under the guidance of Dr. Ciaran Brady and professor Clare Fowler includes patients with advanced multiple sclerosis and problems with bladder function who received a cannabis spray under the tongue.
- In 2001-2003: Phase III studies with about 2000 patients (see also Summary of Trials of GW Pharmaceuticals Ltd's cannabis-based medicines).

3.2 Post-operative pain

- Study led by Dr. Anita Holdcroft, Hammersmith Hospital, London, on effects of cannabis capsules on post-operative pain (Cannador – Marinol – placebo) in 300 patients in a large number of hospitals. Supported by the BMA and British Government (£400,000). It is not clear as to whether the study has actually started.
- Alleviation of post-operative pain after hysterectomy. The study has not yet begun. (See also Summary of Trials of GW Pharmaceuticals Ltd's cannabis-based medicines).

3.3. Other

- Chronic refractory pain or neurological dysfunctions. The study began in May 2000.
- GW may possibly start a study with patients with arthritis, phantom limb pain (PLP) and other complaints.

4. United States

On the political level there is no desire to carry out studies on medicinal cannabis. On the investigator and patient level initiatives may well be taken to carry out studies with medicinal cannabis. There is a great difference in the political climate between the various states concerning medicinal cannabis. Many states approved the medicinal use of cannabis in some way or the other, but the medicinal use is not allowed from the federal level. Approval on the federal level remains a problem for states that want to start investigations. However, the medicine Marinol (which contains dronabinol) is registered in the USA and is prescribed for counteracting nausea in patients who are undergoing chemotherapy and as an appetite stimulant in AIDS patients.

4.1 HIV / AIDS

- Tolerance of marijuana and Marinol in HIV patients during treatment with antiretroviral medicines (the study has been completed and a follow-up study is being planned). Contact: Dr. Donald Abrams, DAbrams@sfajids.ucsf.edu .
- A study on HIV / AIDS with marijuana is to begin shortly. Contact: Dr. Dennis Israelski, Chief of Infectious Diseases at the Hospitals and Clinics of San Mateo County, California; San Mateo County Health Center.
- HIV, cancer, multiple sclerosis (begins shortly). Contact: The Centre for Medical Cannabis Studies, University of California, Dr. Donald Abrams, DAbrams@sfajids.ucsf.edu California, made funds available in September 1999 for four research programmes at the Universities of California in San Francisco and San Diego. Investigations are to be carried out to determine whether smoking of marijuana alleviates neuropathy in AIDS, diabetes and pain. One study will be made on hospital patients, the other on patients staying at home. A third study will investigate the effect of use of cannabis as a medicine on motor performance of patients with the aid of a driving simulator. The fourth study will investigate spasticity in multiple sclerosis. This study seems to be approved by the federal authorities in December 2001. The cannabis is to be supplied by the University of Mississippi.

4.2 Chemotherapy

6 States have listed existing data on nausea and vomiting after chemotherapy in cancer patients. This involved a total of 748 patients who smoked non-standardised cannabis before and/or after their chemotherapy and 345 patients who swallowed the THC capsules. The first group experienced 70-100% alleviation and the second group 76-88 % alleviation.

4.3 Glaucoma

Dr. John Merritt (California) has carried out many studies on glaucoma with medicinal cannabis.

4.4 Migraine

A study on migraine has been approved but no financing is available. Contact: Dr. Ethan Russo, erusso@blackfoot.net

5. Germany

The German Federal High Court stated in 1999 that medicinal use of cannabis could be subject of a licence in accordance with art. 3 paragraph 2 of the Narcotics Act in special cases. Up to now about 120 private persons applied for a licence for personal medical use but each application has been

rejected by the Federal Opium Agency. One of the reasons for rejecting was a licence would involve the use of illegal, non-standardised cannabis, for which no proof of effectiveness can be given.

- Study on Gilles de la Tourette syndrome by the Hanover Medical School. A pilot study with Marinol and placebo in 12 adults on the effect of delta-9-TCH (DB-CO-PC) has recently been completed. Contact: Dr. Kirsten Müller-Vahl, mueller-vahl.kirsten@gmx.de . A double blind placebo-controlled study with 2 x 12 patients is to be started shortly.
- Study in the Netherlands – Germany – Switzerland – (Austria?) on the effect on weight loss in AIDS and cancer patients. (Cannador – Marinol – placebo). Contact: Dr. Martin Schnelle, martin.schnelle@eifoi.de . Dr. Gorter is also assisting here.

6. Switzerland

Switzerland is operating a progressive drugs policy and, like the Netherlands, makes a distinction between hard and soft drugs. In Switzerland there is also a progressive attitude to medicinal cannabis.

- A study with Cannador, Marinol and placebo in multiple sclerosis was completed in the Spring of 2001. Contact: Dr. Claude Vaney, Vaney.Claude@bernerklinik.ch .
- Study on local (topical) administration of cannabinoids. Spasticity in intractable lesion. A study with Marinol and placebo is in progress. Contact: Dr. Ulrike Hagenbach, a.u.hagenbach@balcab.ch .
- Study on the analgesic effect of THC under experimental pain conditions. Contact: Prof. Dr. R. Brenneisen, brenneisen@dkf5.unibe.ch
- Phase II cannabis trial for safety and tolerability of cannabis extract in palliative cancer patients. Contact: Dr. J. Hoffmann, Lukas Clinic
- Study to compare the efficacy of cannabis extract and dronabinol on appetite and weight in cancer patients. Contact: Dr. D. Betticher, Int. For Medical Oncology, University Hospital Berne

7. Spain

The Catalan Parliament has submitted a bill for legalising medicinal use of cannabis. The bill is supported by all Members of Parliament and would permit the use of cannabis for treating AIDS, arthritis and glaucoma, etc. The initiative came from a group of women with breast cancer who found that cannabis is an important anti-emetic.

In November 1999 Andalusia announced that it will be permitting research on the use of cannabis in AIDS, cancer and asthma. Several other Regional Parliaments are also saying that they want to permit medicinal use.

8. Finland

David Pate, Department of Pharmaceutical Chemistry, University of Kuopio is carrying out studies on glaucoma (in collaboration with Hortapharm).